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McKinnon et al.

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(54) **ELECTRONIC MONITORING MEDICATION APPARATUS AND METHOD**

FOREIGN PATENT DOCUMENTS

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WO 99/35588 7/1999 (WO).

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(57) **ABSTRACT**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

A system for dispensing medication includes: a medicine canister that contains medicine to be dispensed, an actuator that houses the medicine canister and an adapter assembly that allows for obtaining information. The adapter assembly includes a connector assembly and an electronics module. The connector assembly connects to the medicine canister. The electronics module obtains information related to patient usage of medicine from the medicine canister. In another embodiment, a method for using the same electronics module with first and second medicine dispensing apparatuses, including a first medicine canister and a second medicine canister, is provided. The first medicine canister contains first medicine and the second medicine canister contains second medicine. First information, related to dispensing the first medicine, is stored with the electronics module joined to the first medicine dispensing apparatus. The electronics module is removed from the first medicine dispensing apparatus and joined to the second medicine dispensing apparatus. Second information, related to dispensing the second medicine, is also stored with the electronics module.

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(22) Filed: **Apr. 23, 1999**

(51) **Int. Cl.**⁷ **A61M 11/00**

(52) **U.S. Cl.** **128/200.23**; 128/200.16; 128/200.19; 128/204.23; 128/203.12; 128/205.23; 128/204.21; 128/200.14

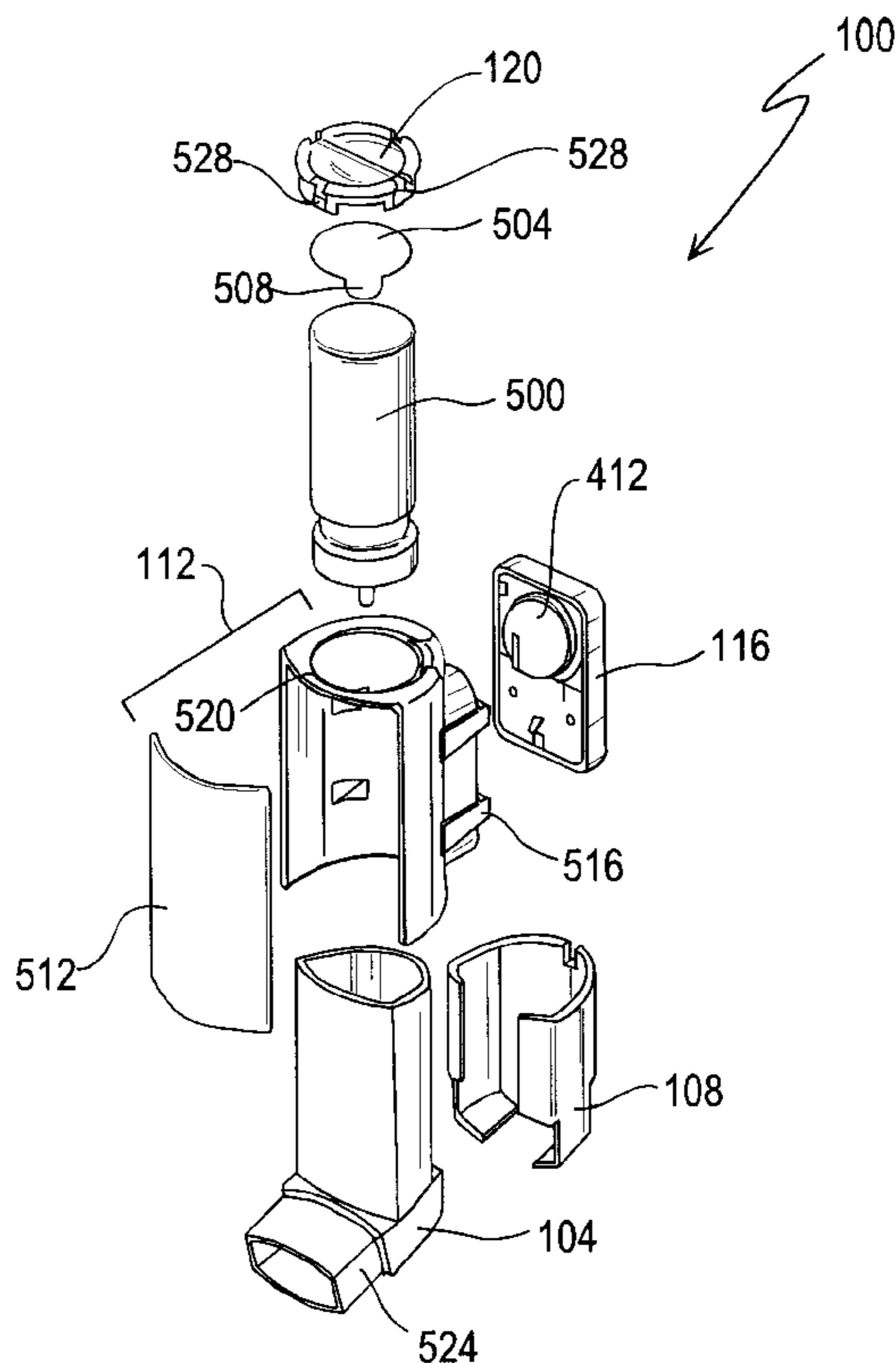
(58) **Field of Search** 128/200.23, 200.16, 128/200.19, 204.23, 203.12, 205.23, 204.21, 200.14

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14 Claims, 17 Drawing Sheets



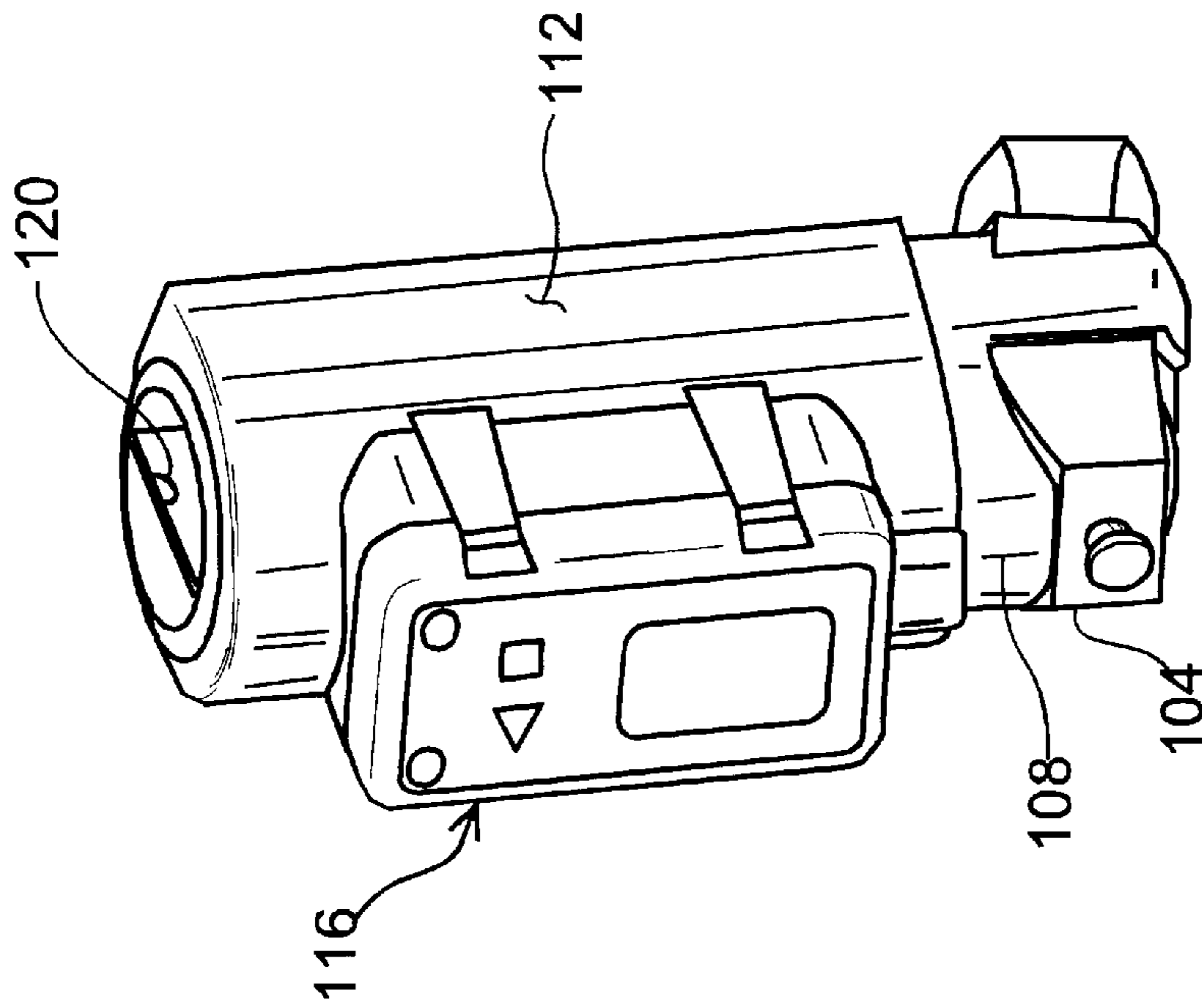


FIG. 2

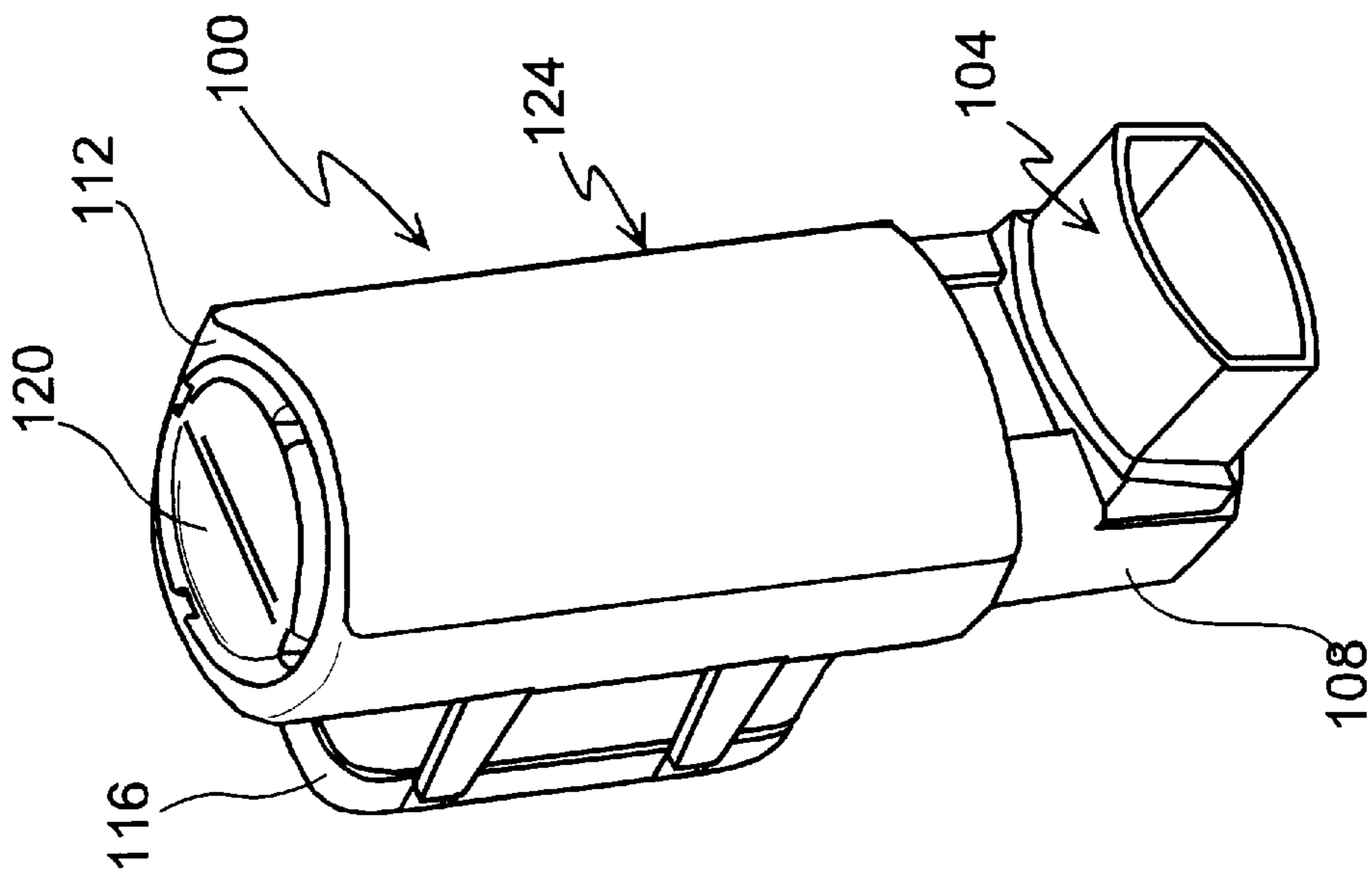


FIG. 1

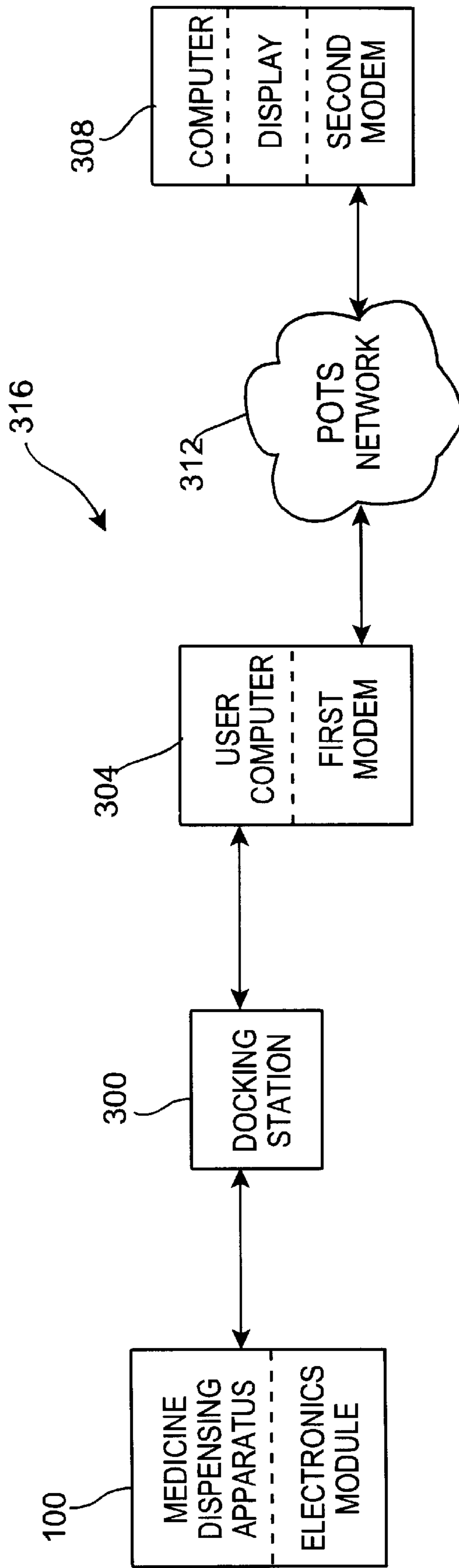


FIG. 3

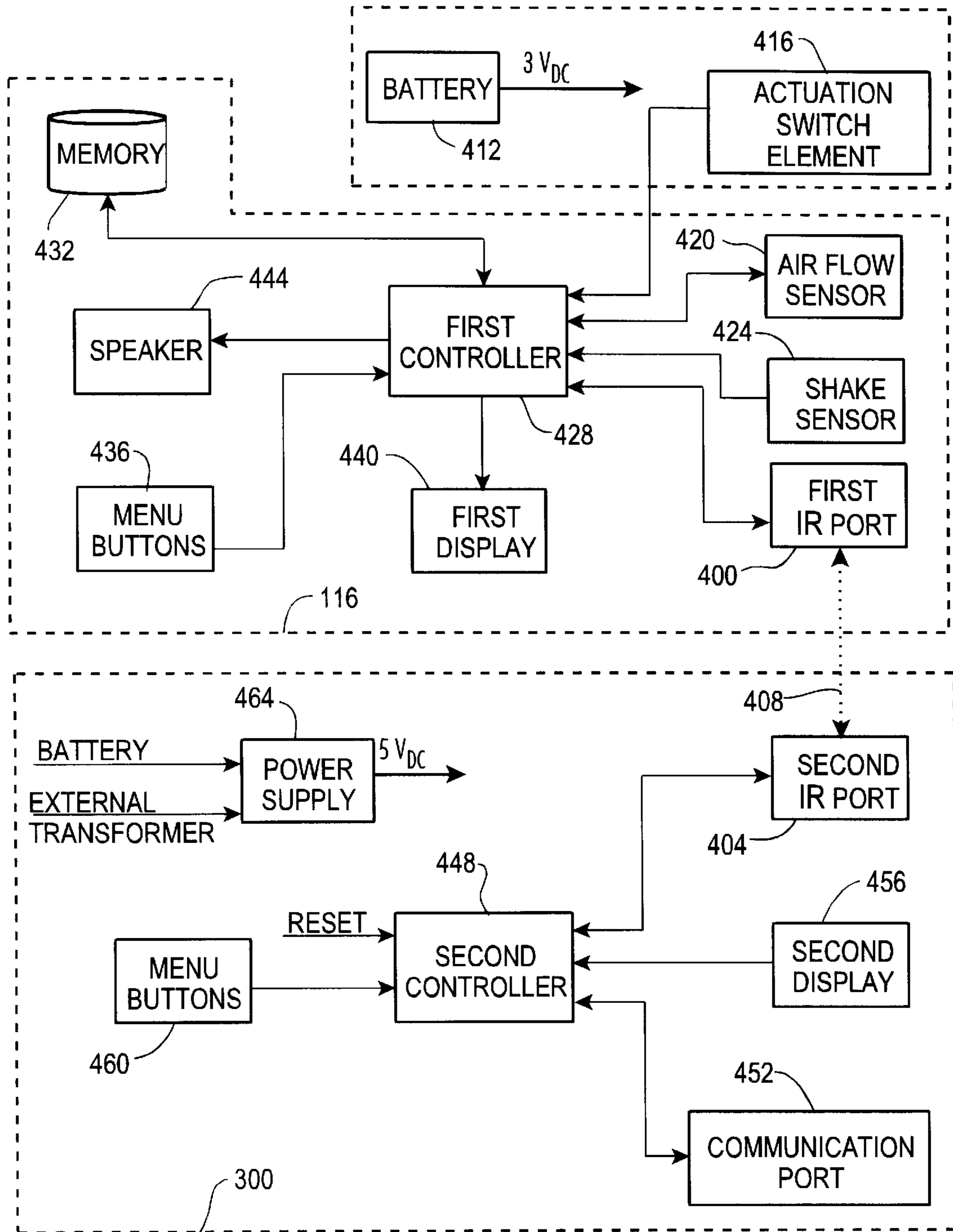


FIG. 4

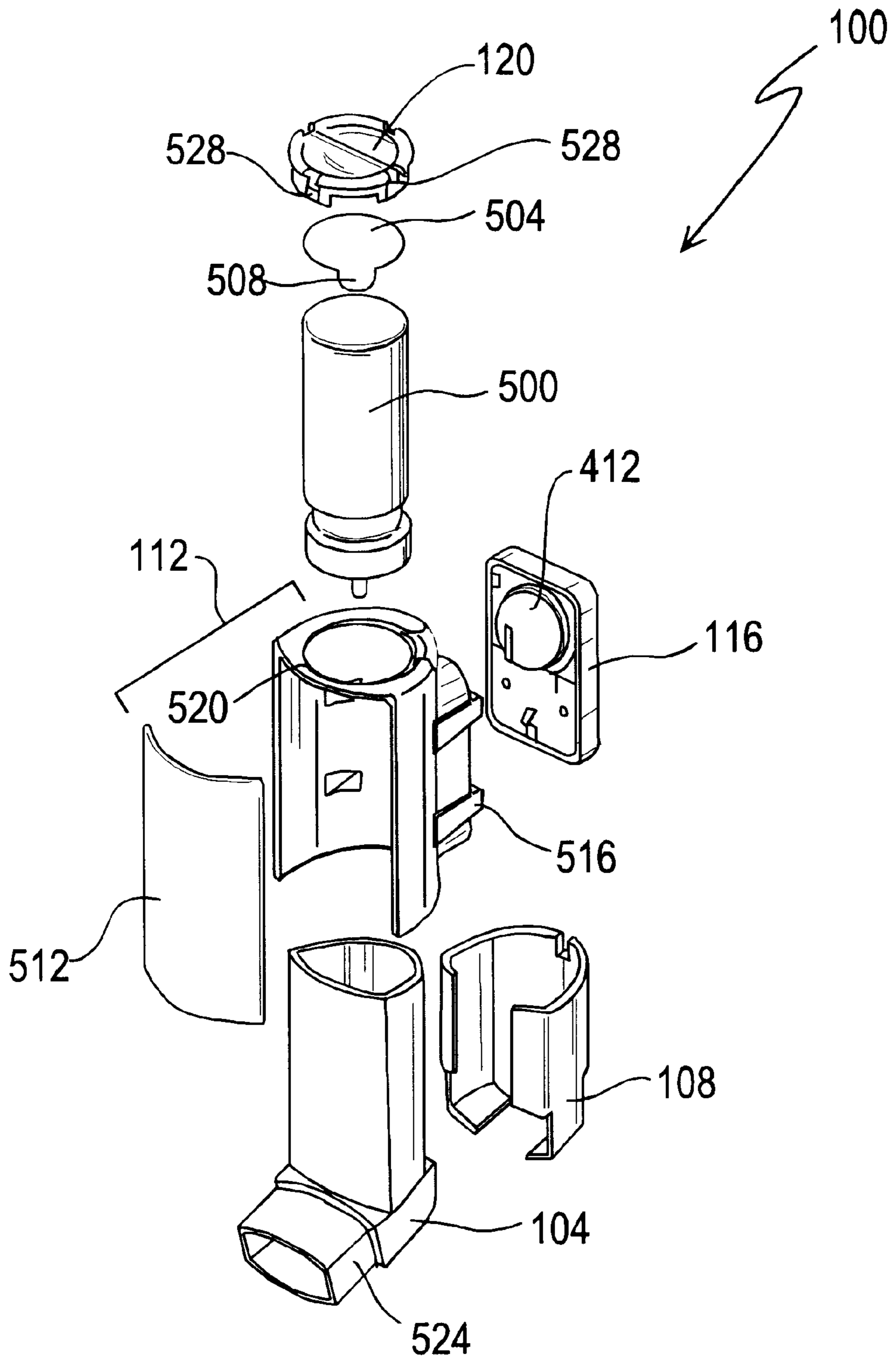


FIG. 5

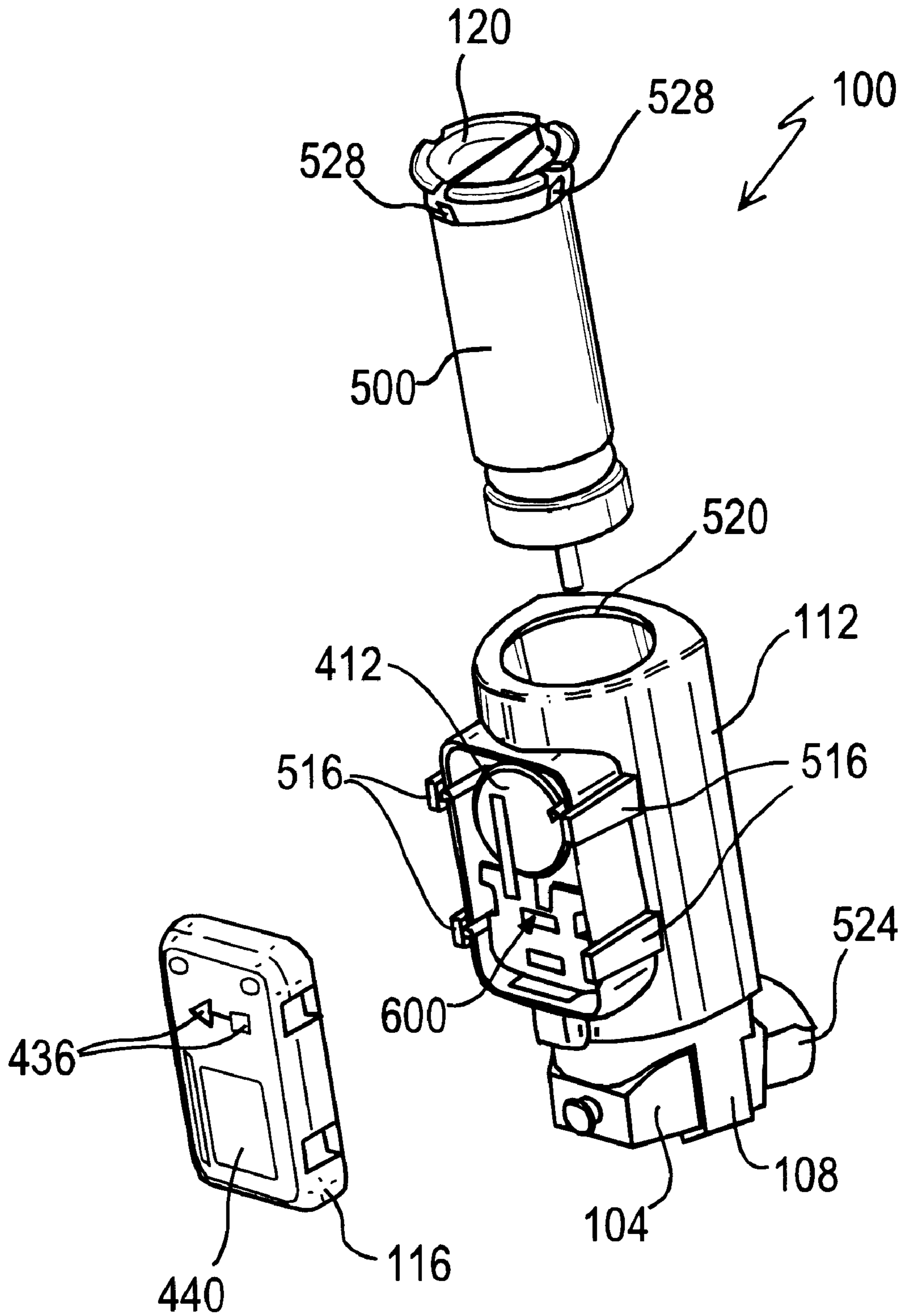


FIG. 6

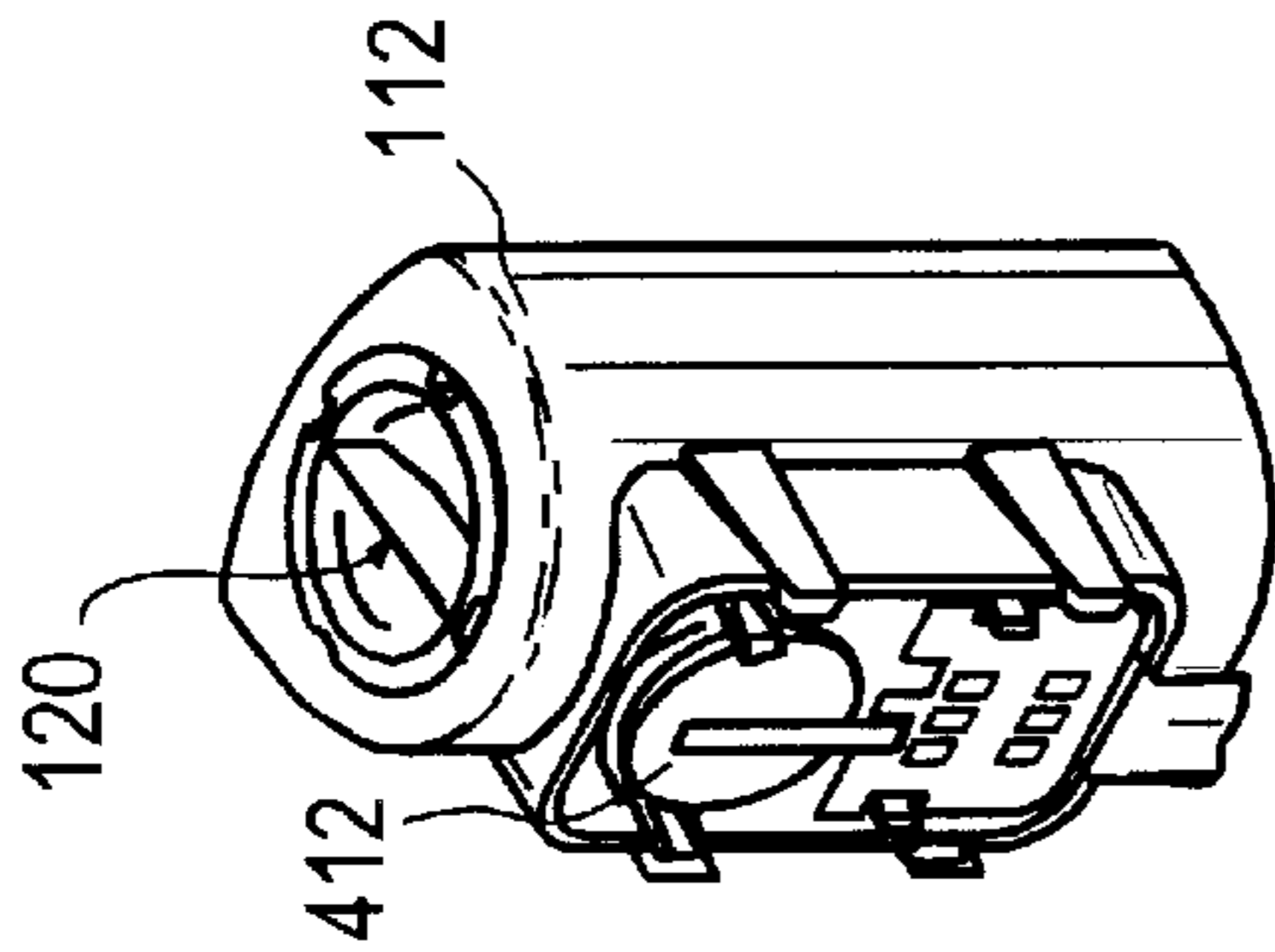


FIG. 7

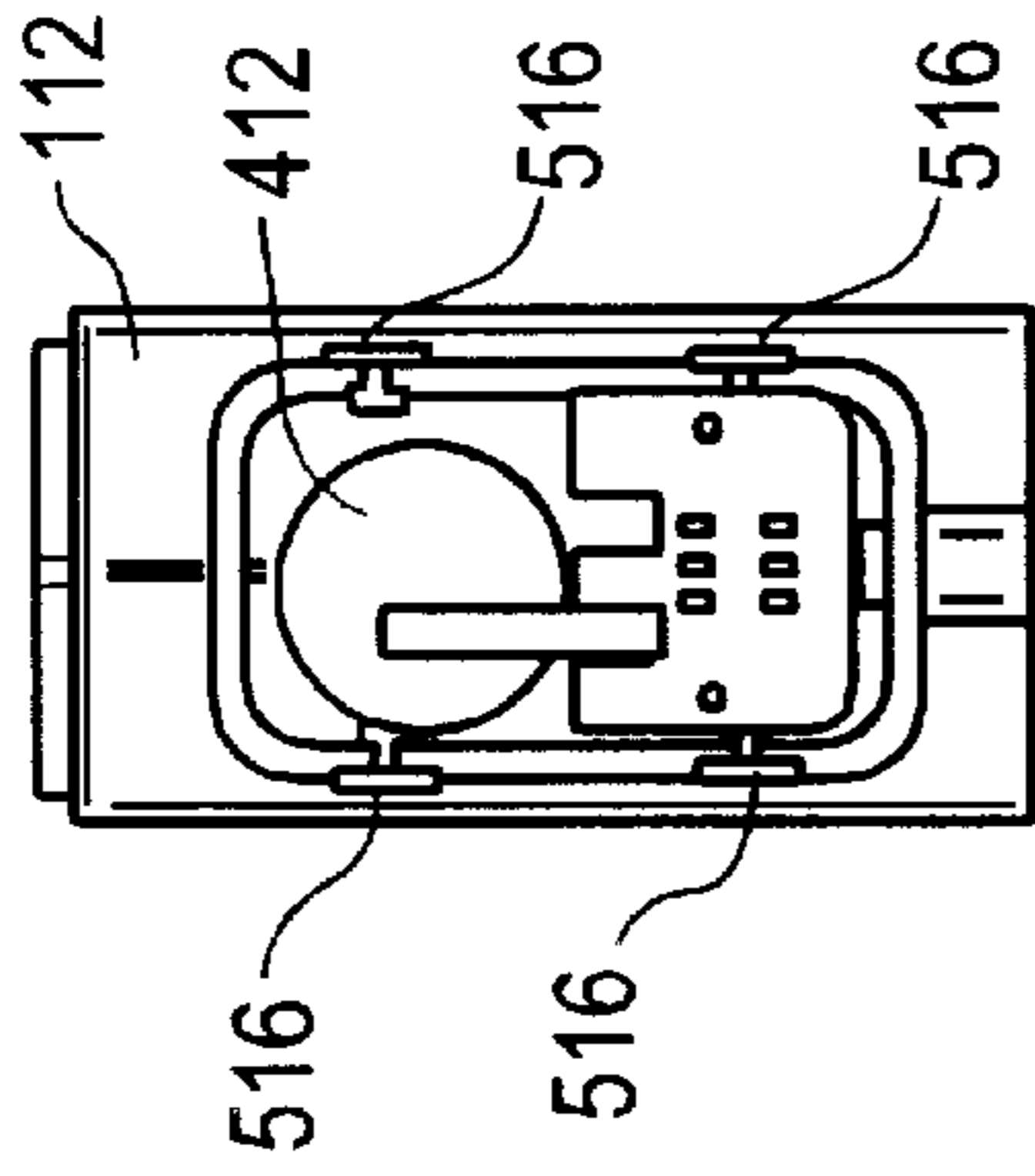


FIG. 8

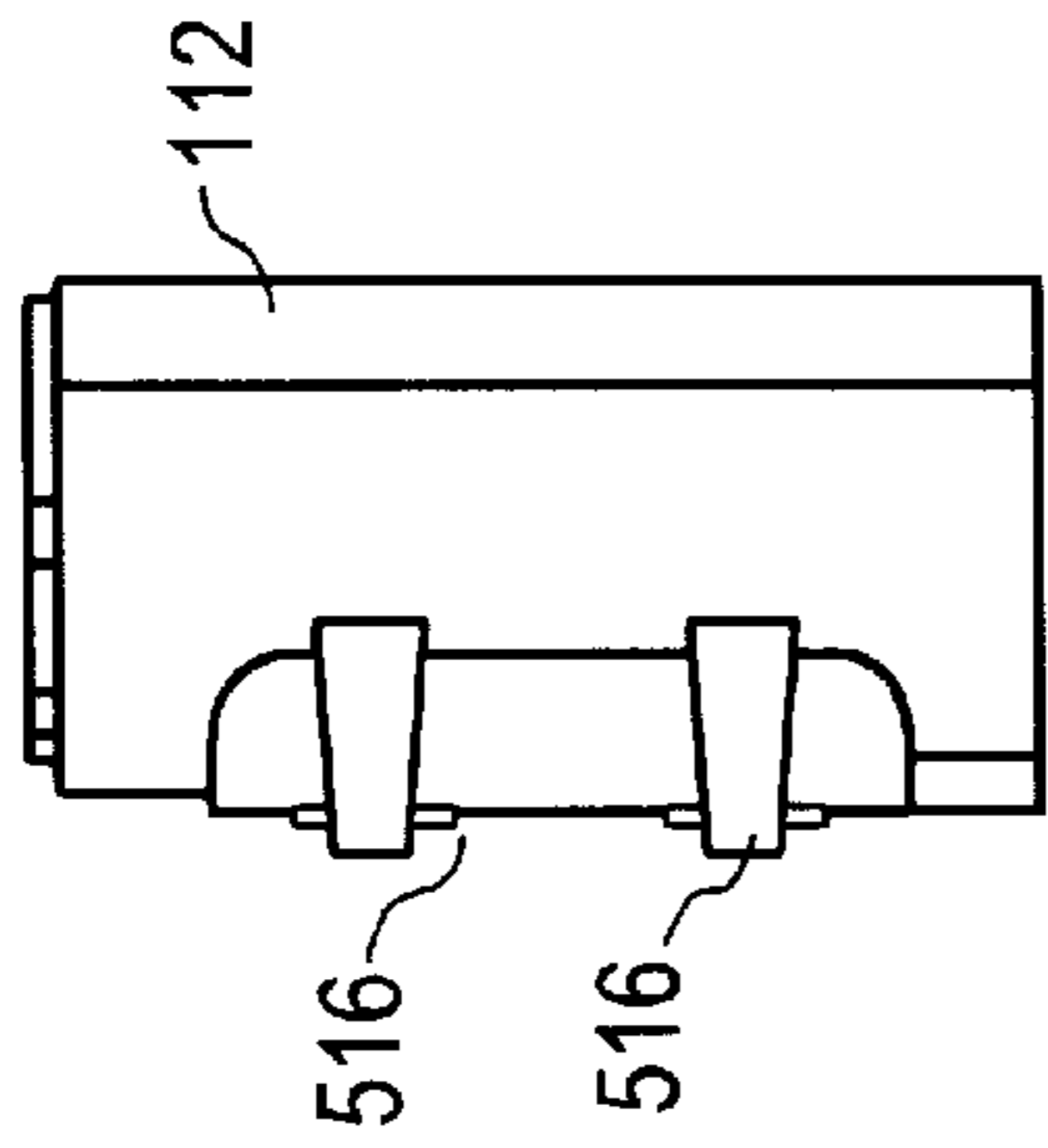


FIG. 9

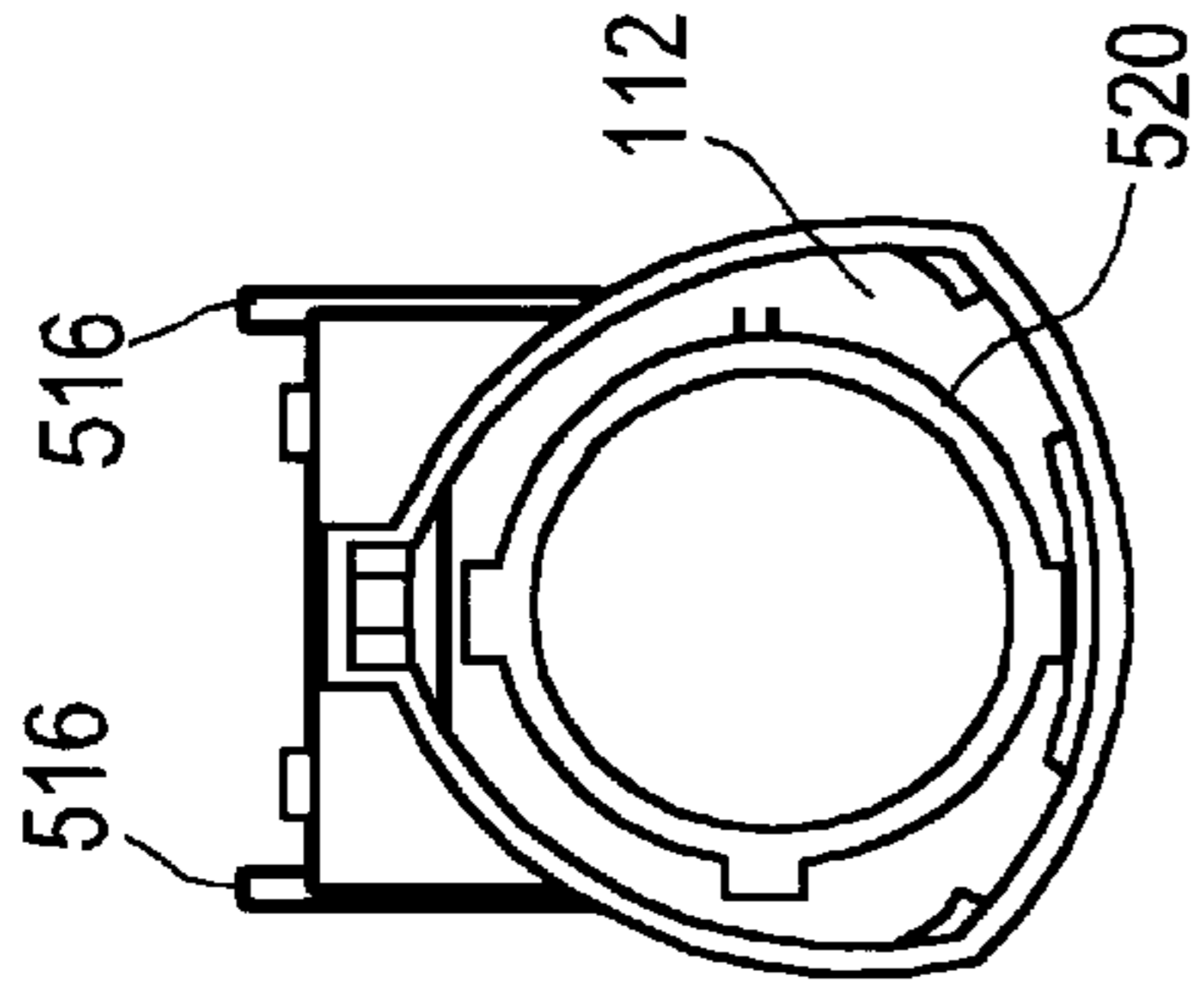


FIG. 10

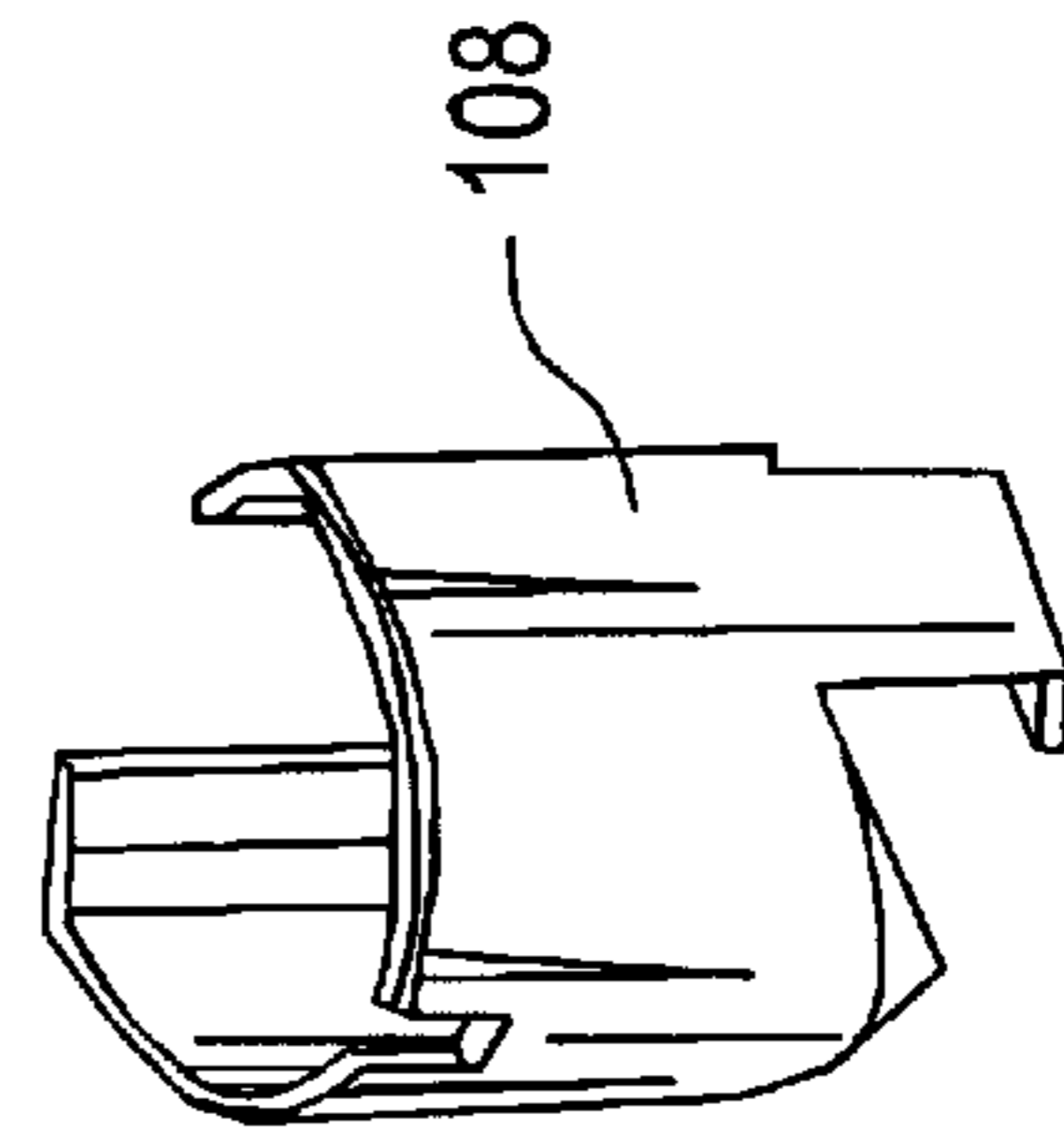


FIG. 11

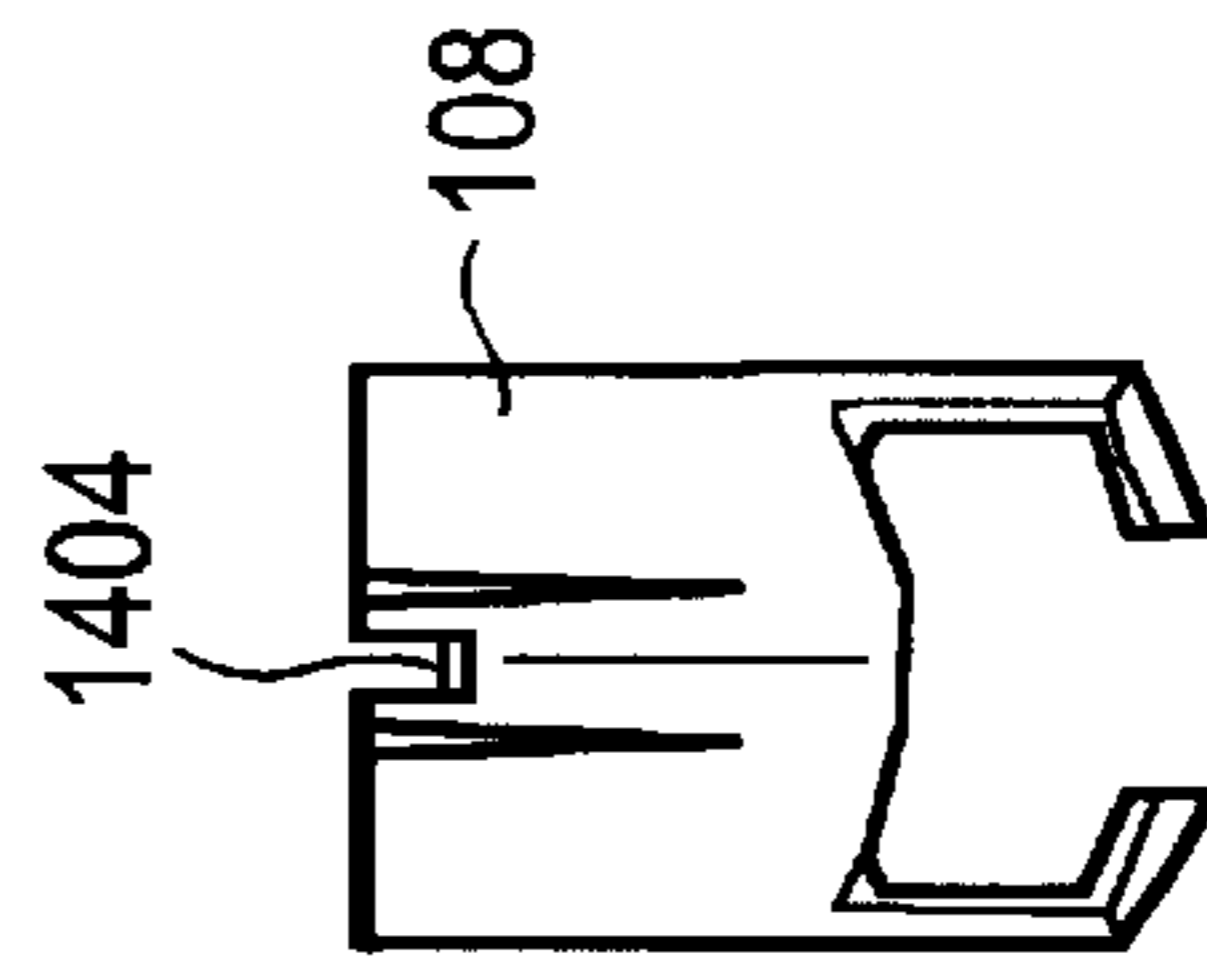


FIG. 12

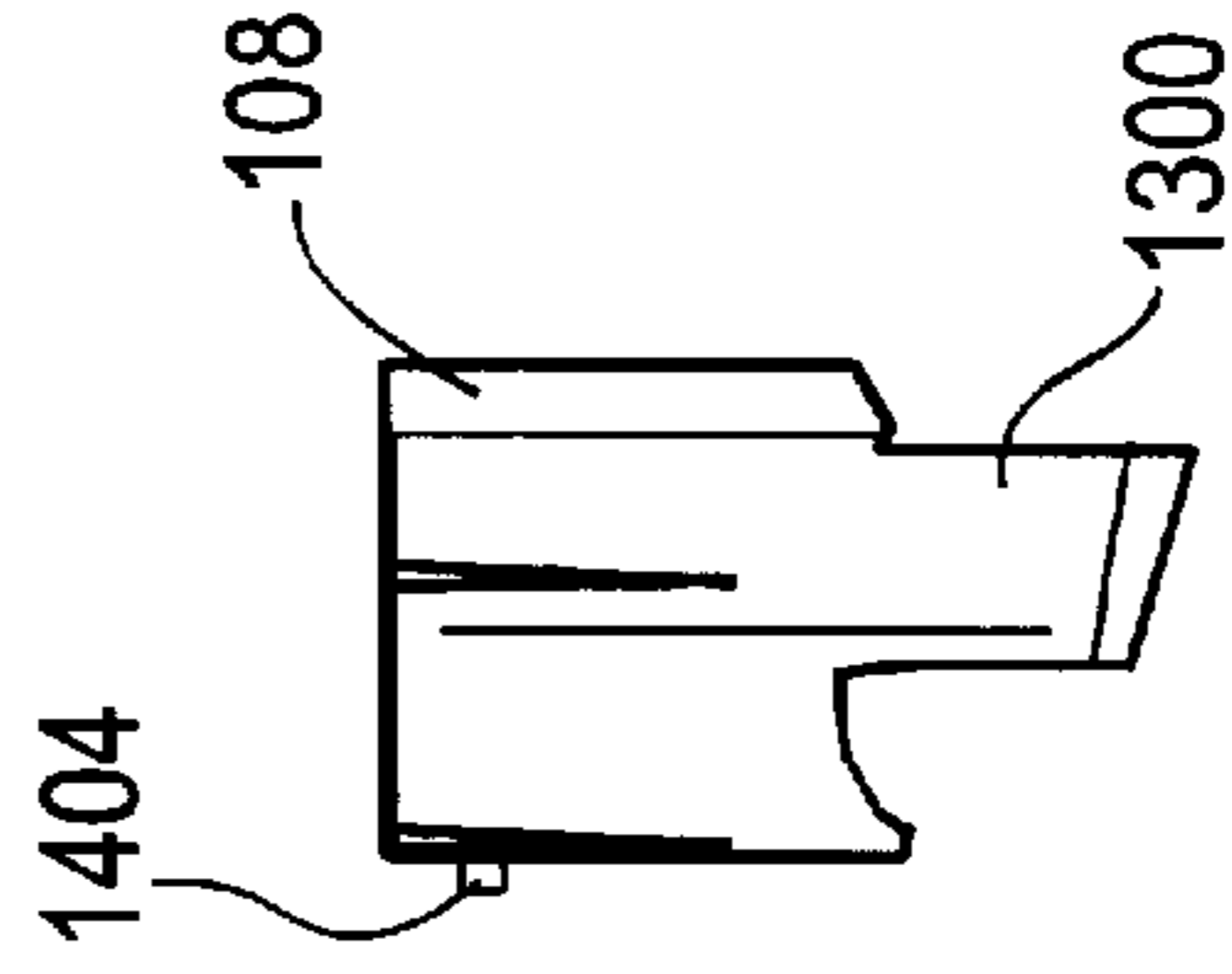


FIG. 13

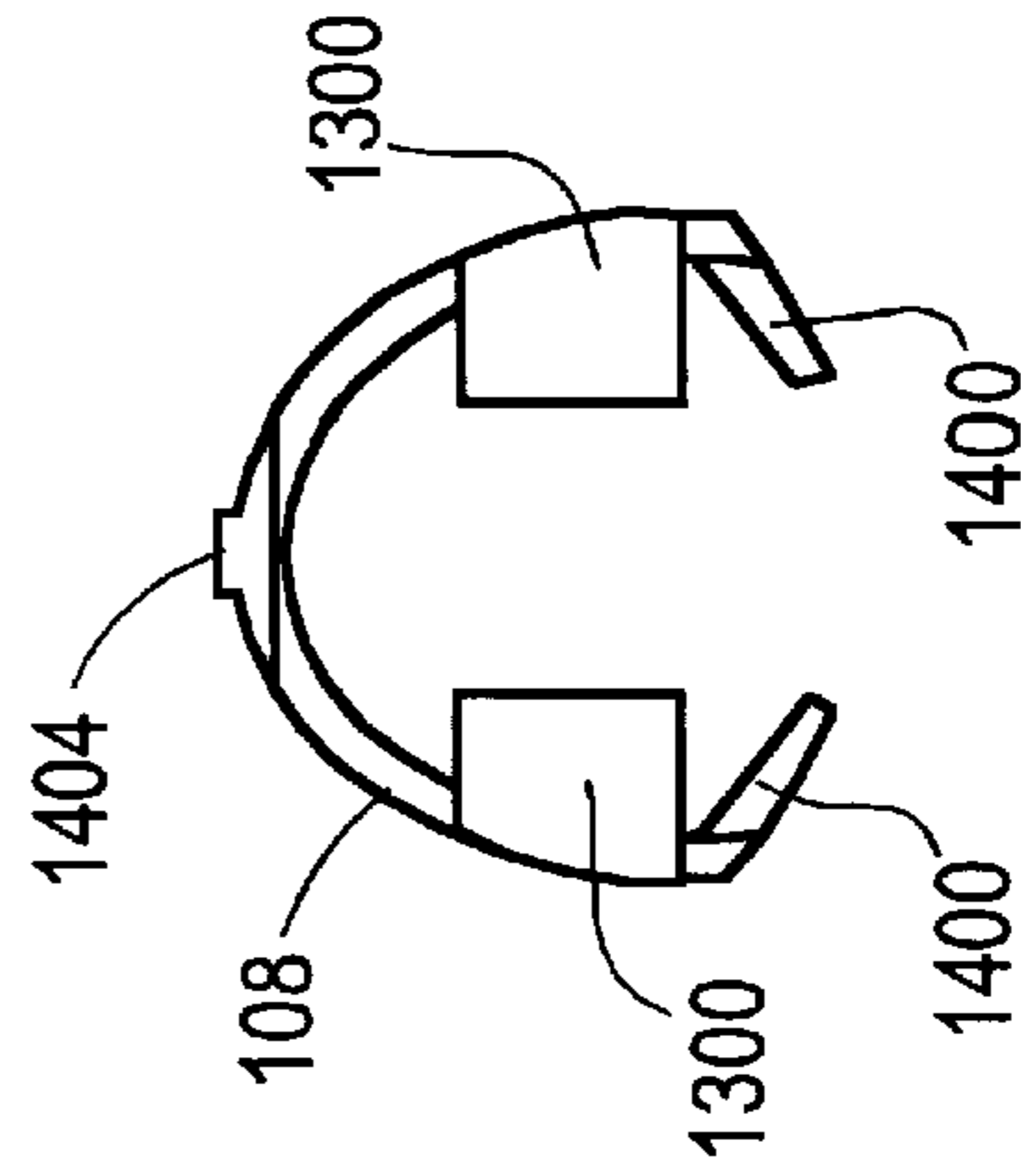


FIG. 14

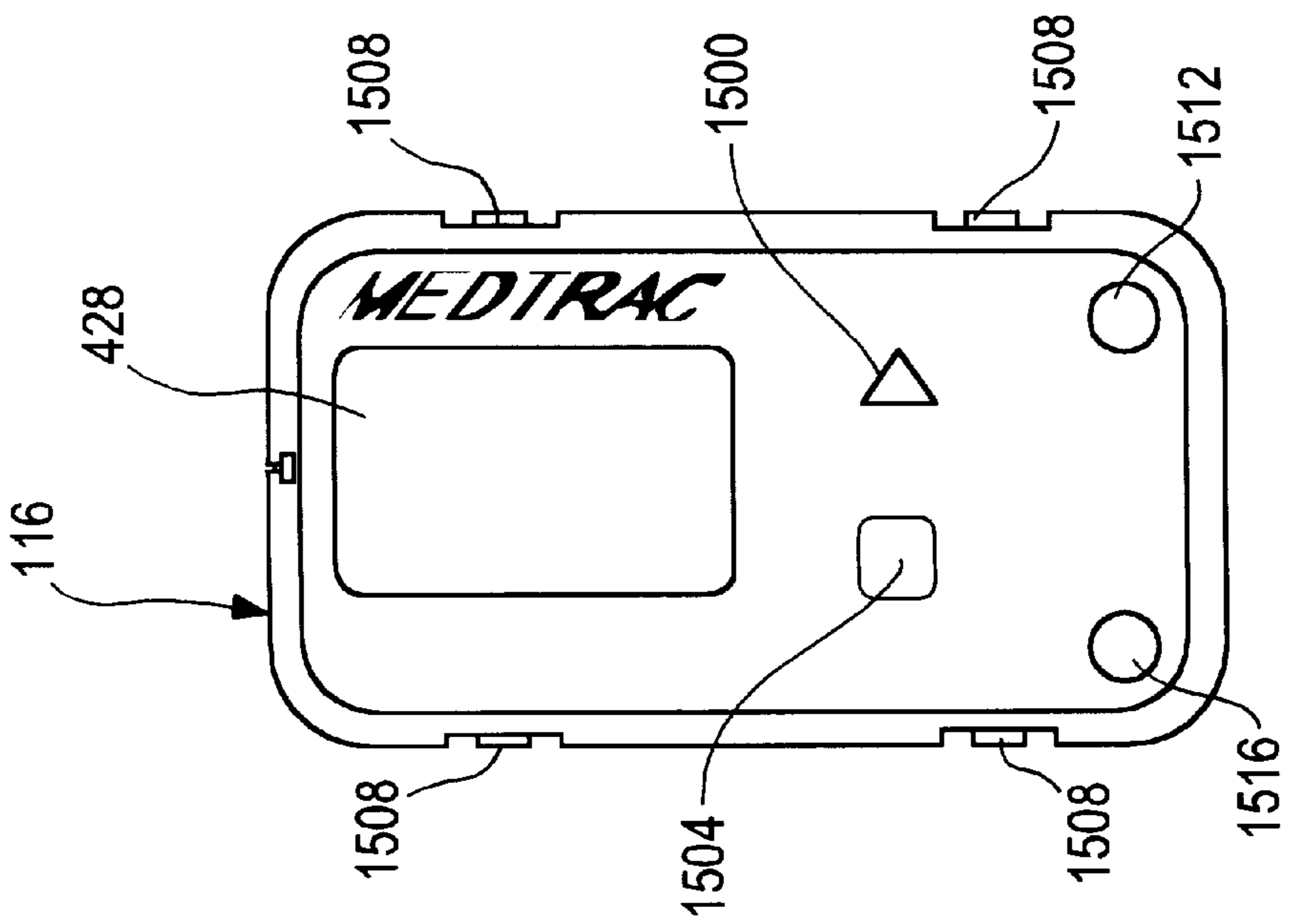


FIG. 15

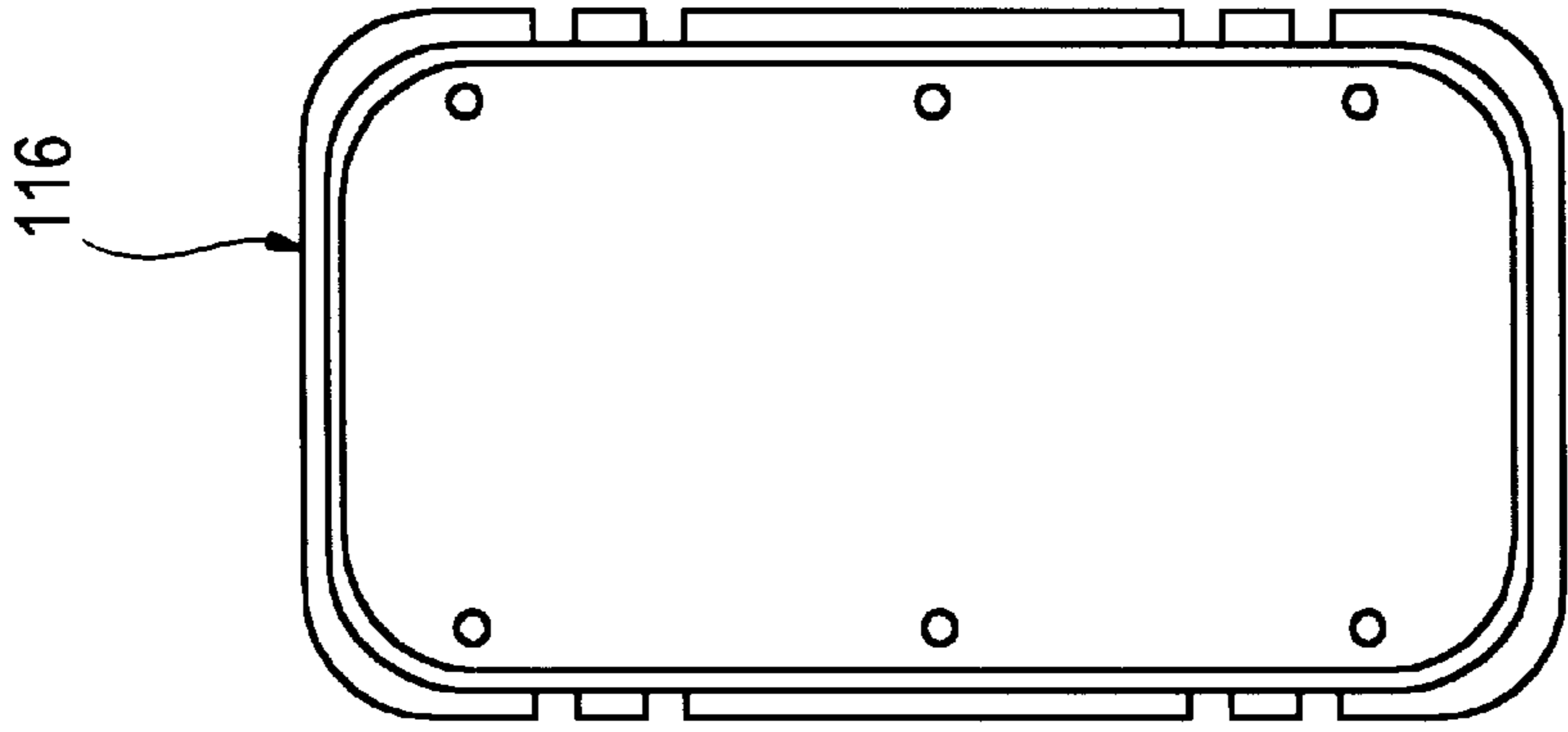


FIG. 16

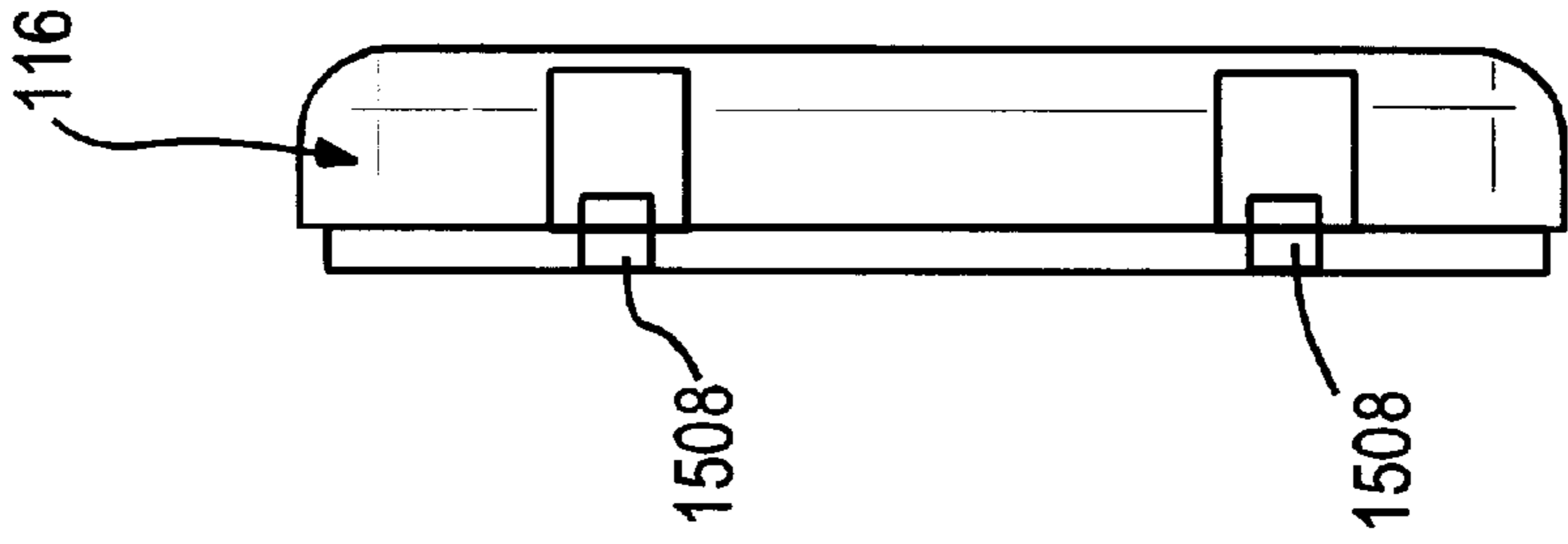


FIG. 17

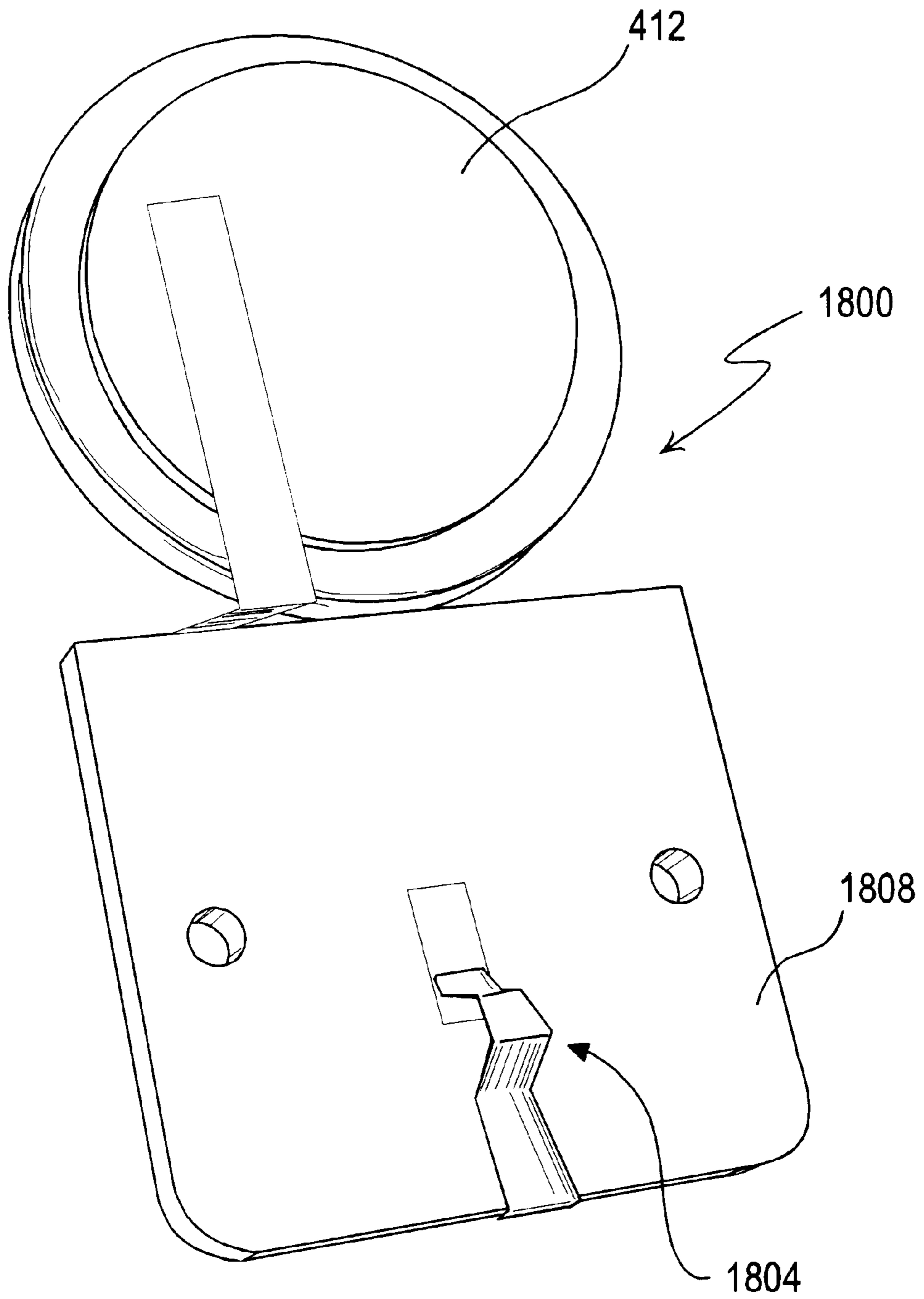


FIG. 18

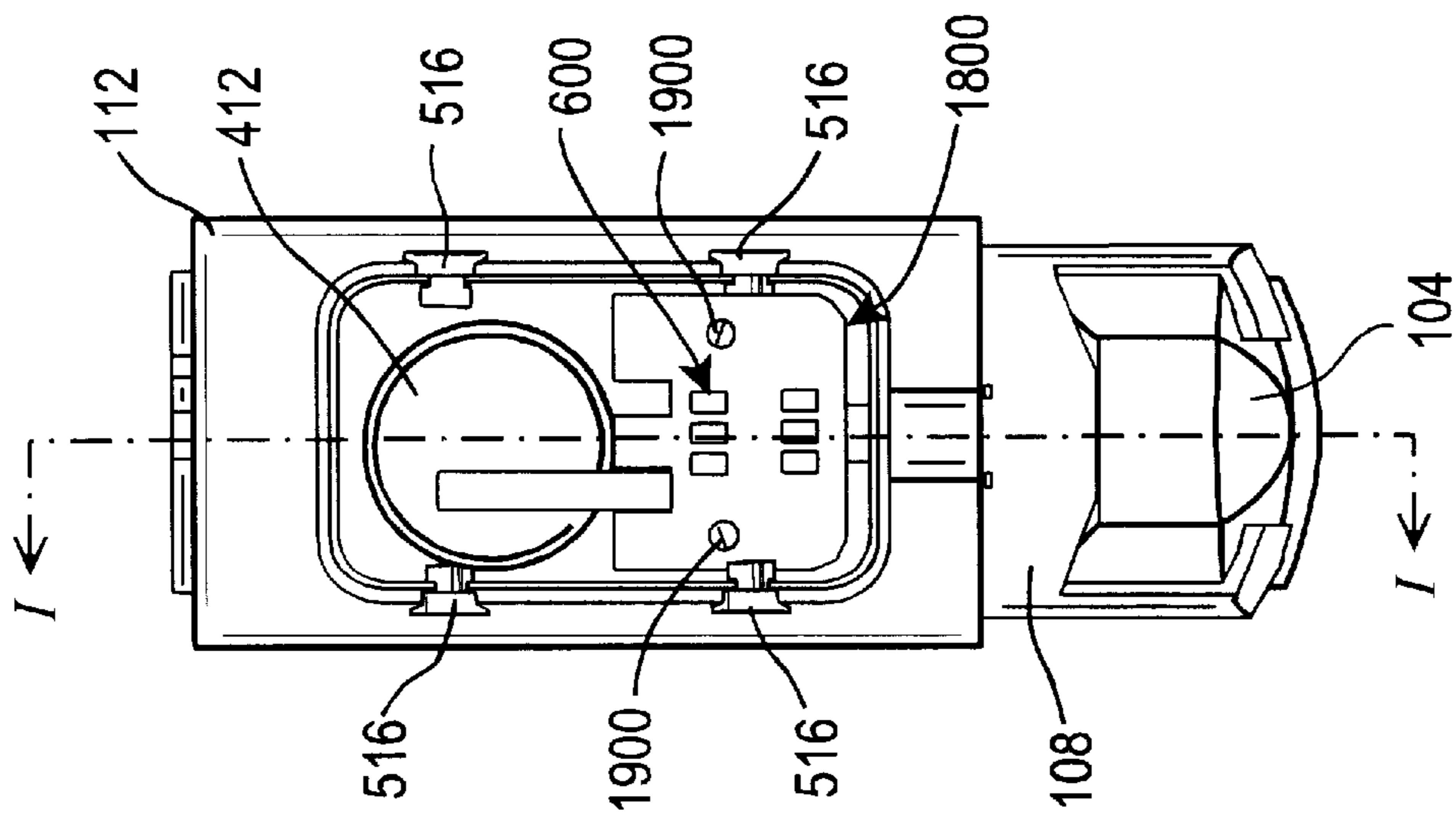


FIG. 19

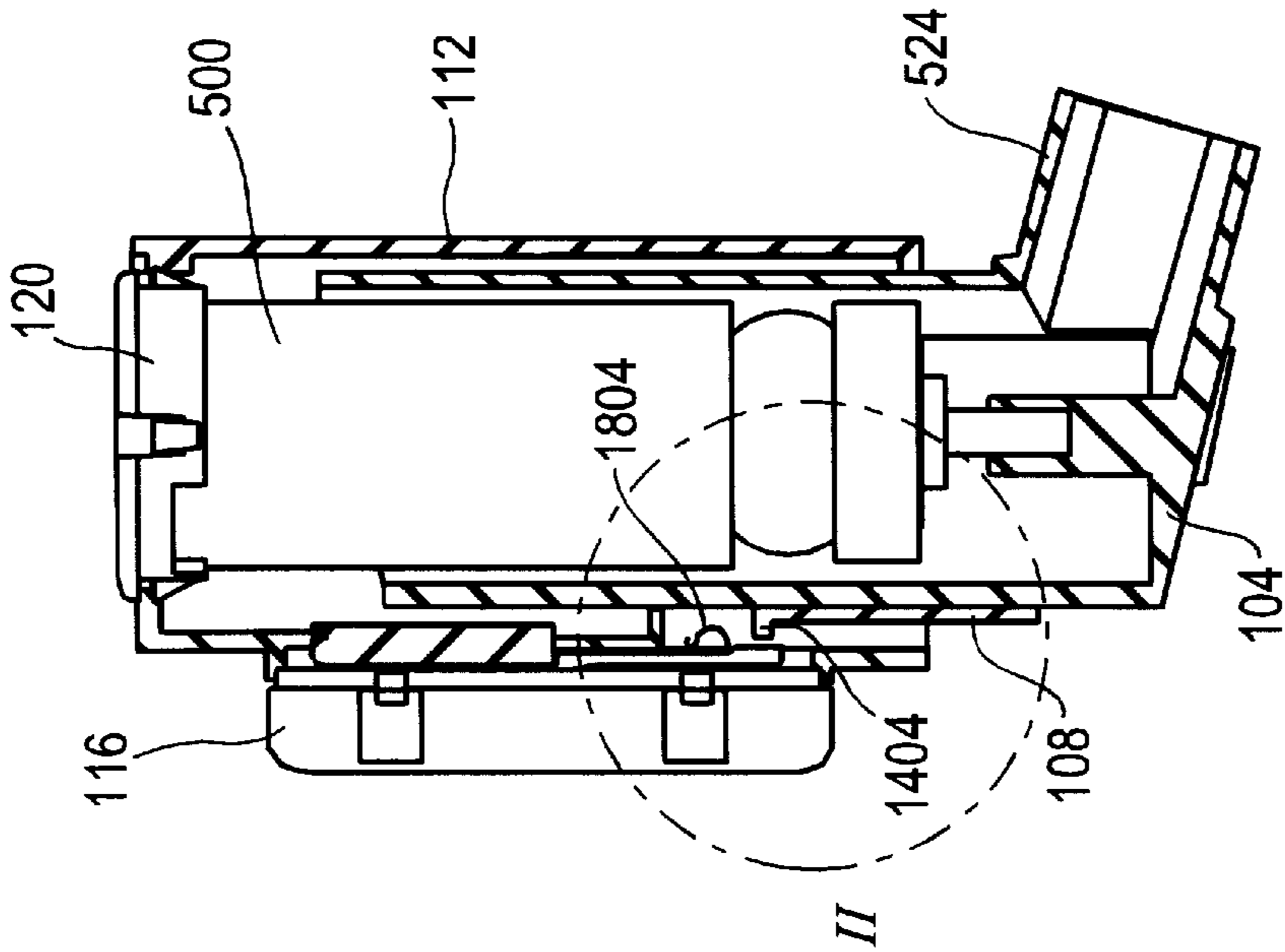


FIG. 20

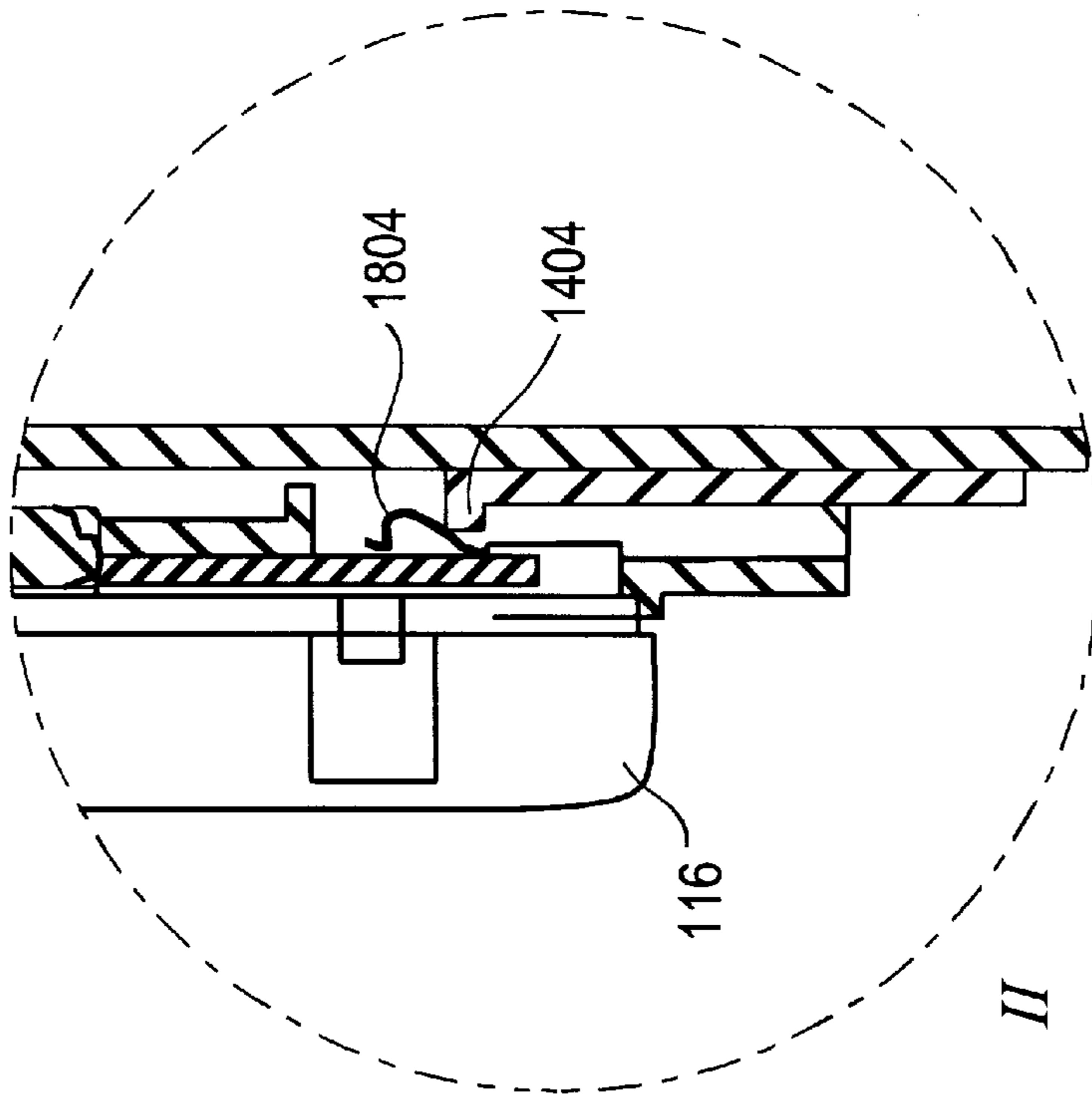


FIG. 21

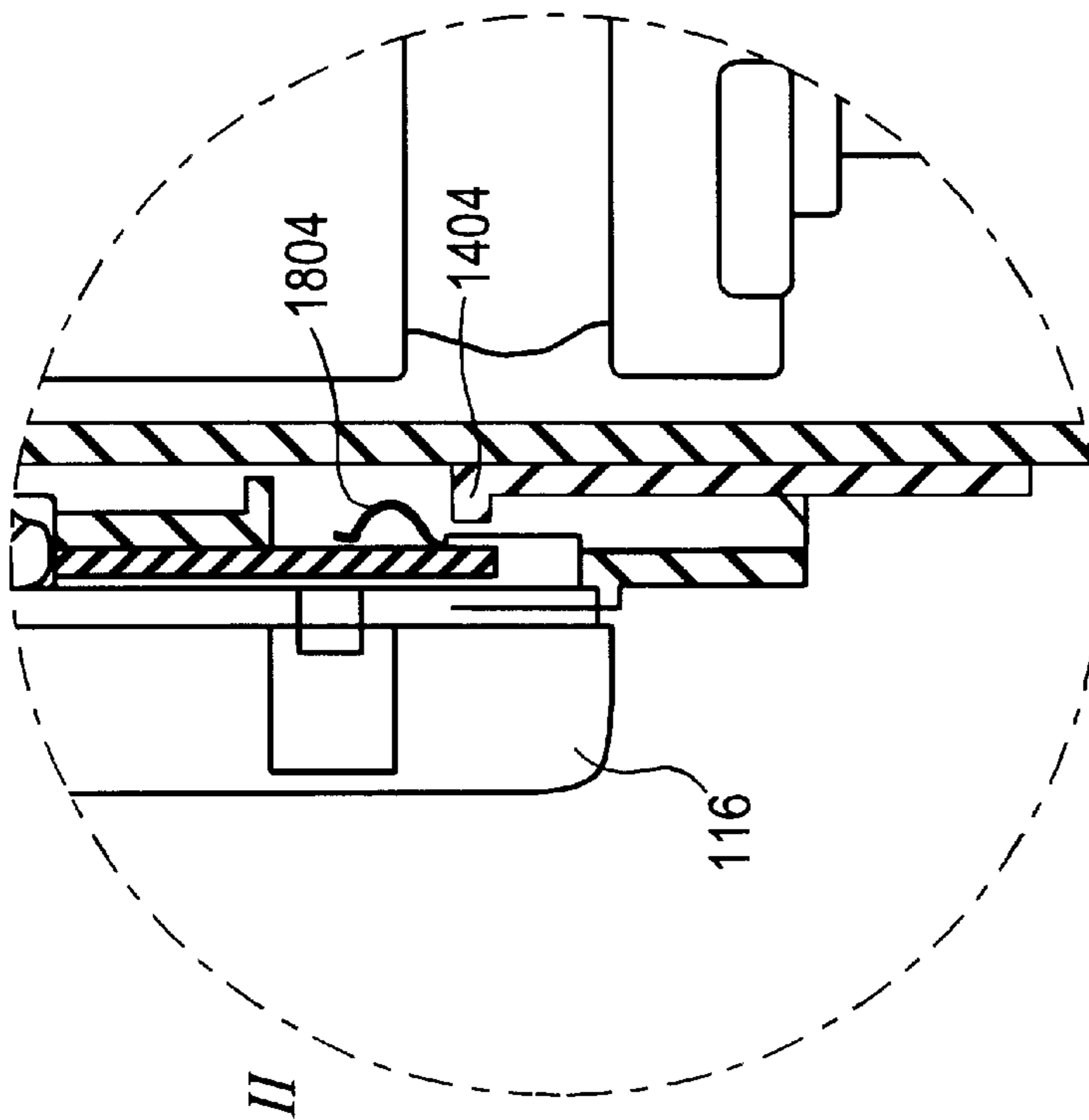


FIG. 22

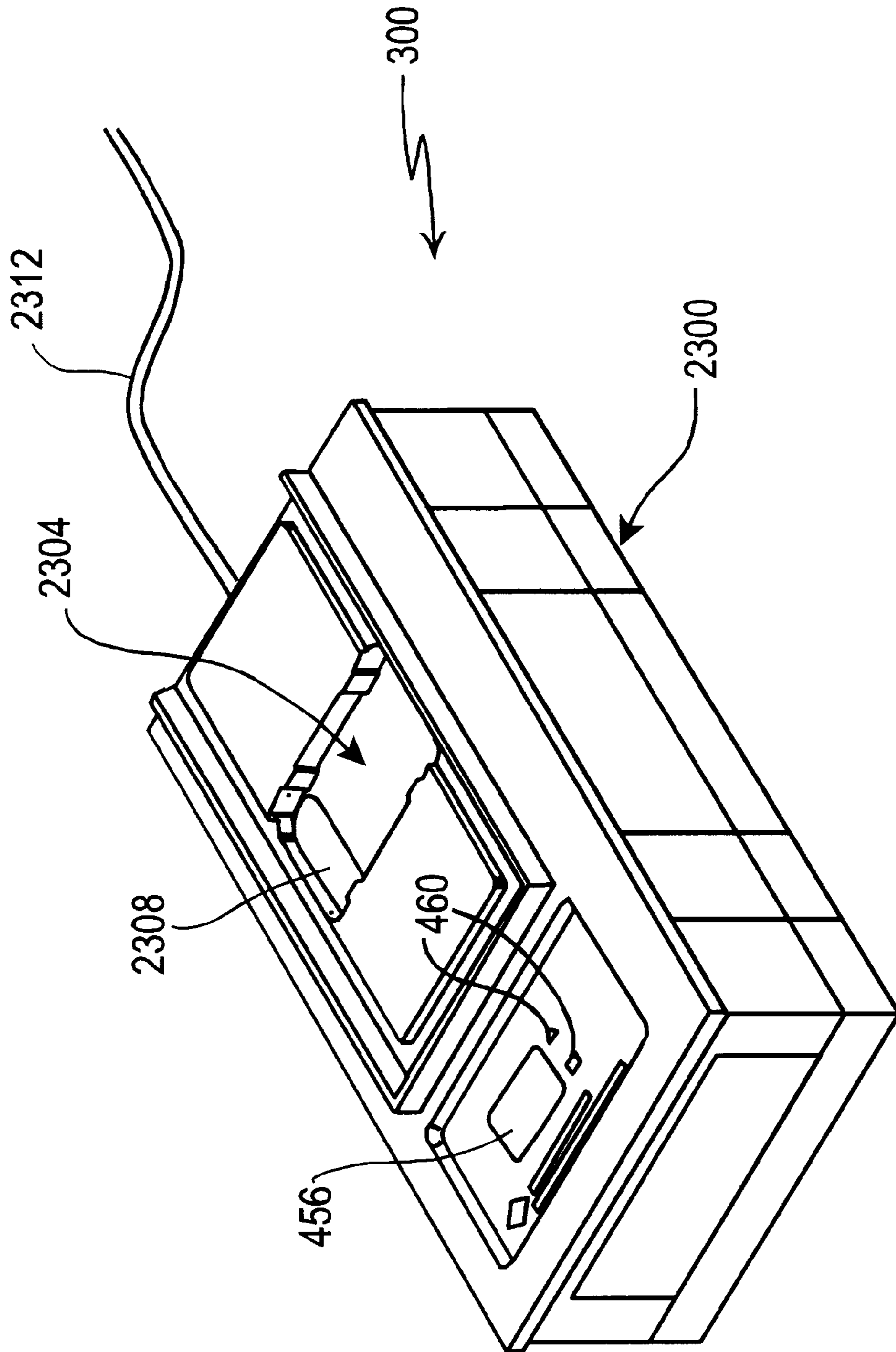


FIG. 23

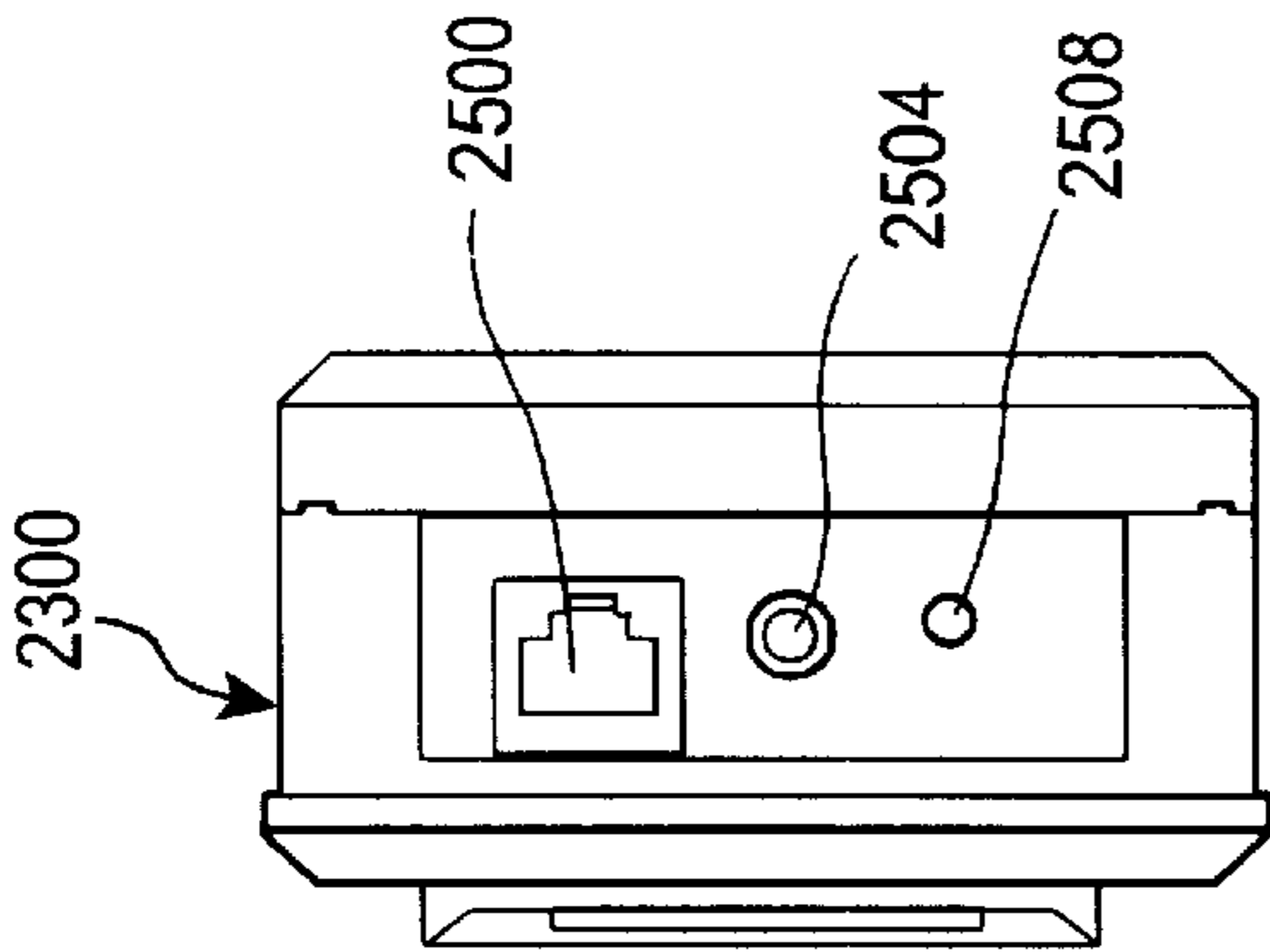


FIG. 25

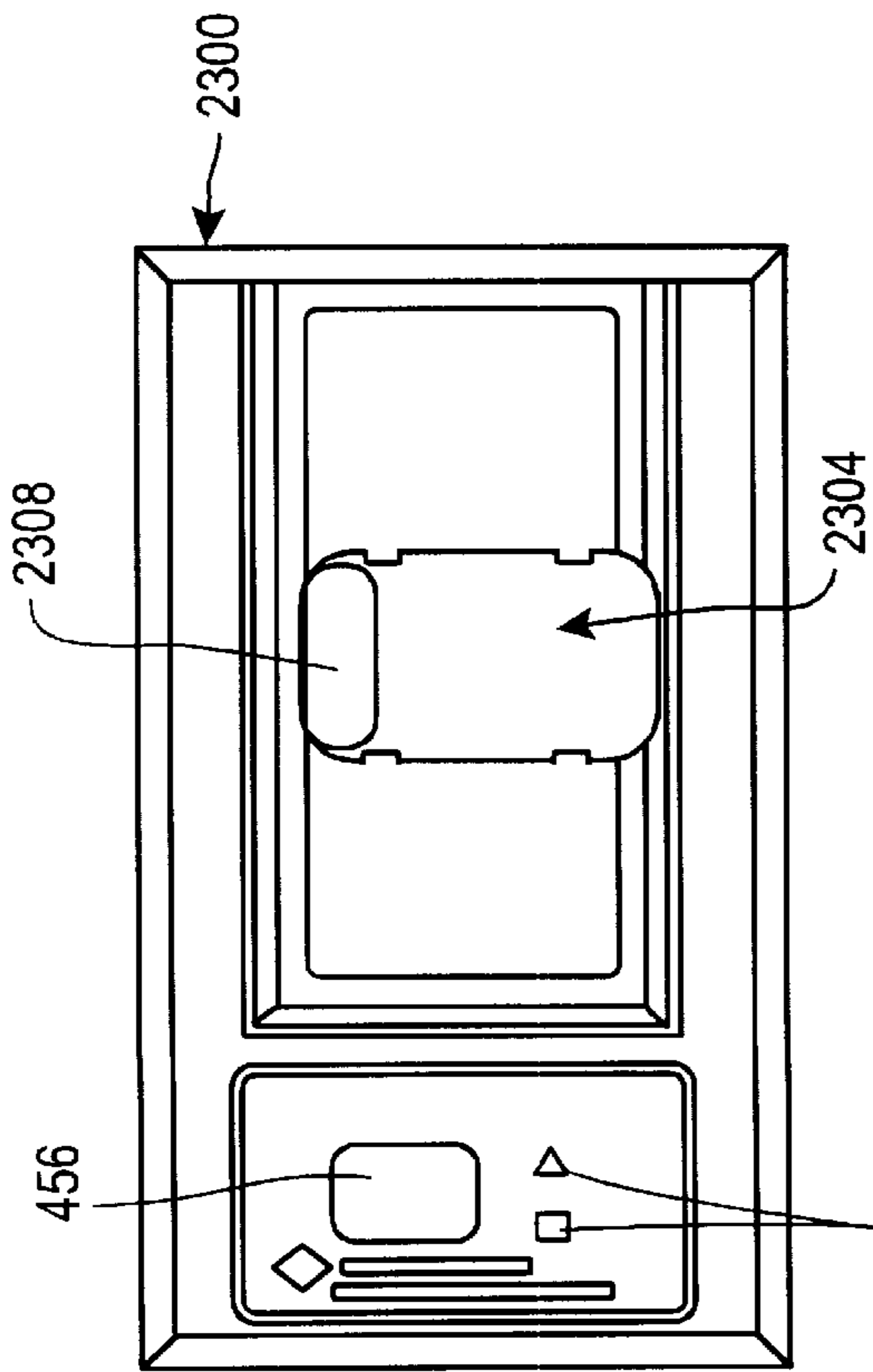


FIG. 24

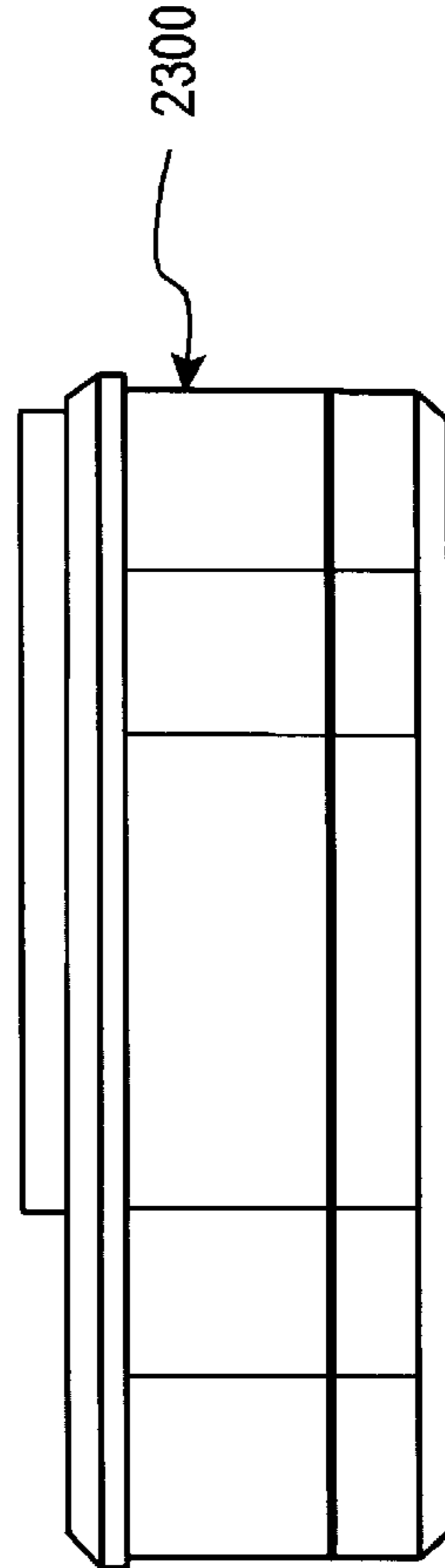


FIG. 26

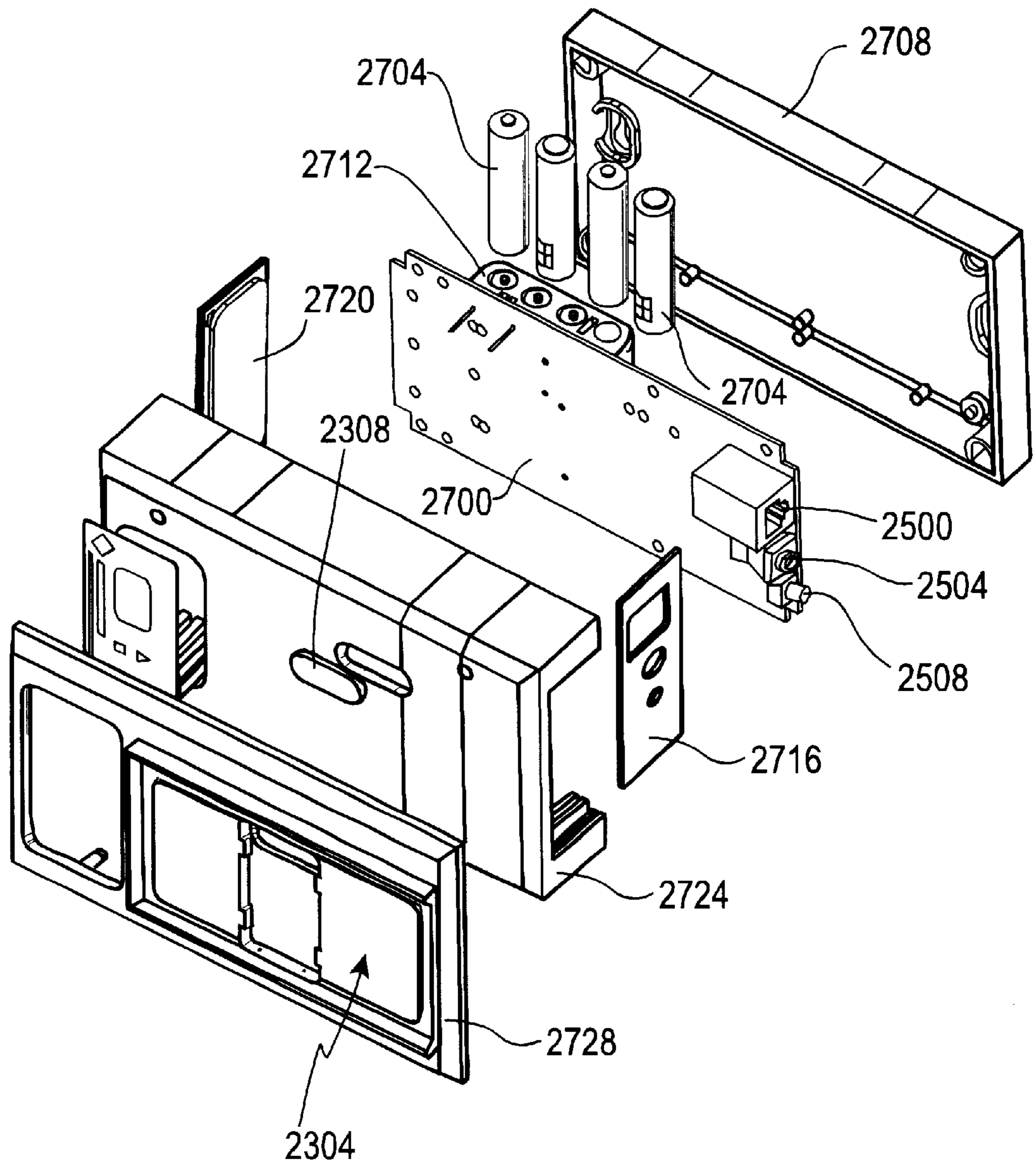


FIG. 27

RxLog - Bradley Jackson

Device Charts Data Patients Notes

Patient Name: Bradley Jackson
Patient ID: jack
Serial No: 0427002
Device ID:

MDILog

Options

- Basic Functions
- Time Functions
- Device Messages
- Patient Info
- Audio On
- Spacer

MDILog Treatment

Medication

Serevent
Compliance Type: As Needed (PRN)
Dispenses Per Canister: 0000

Dosage

Doses Per Day: 3
Puffs Per Dose: 2
Time Between: 04:00

Reminders

#1: 00:00
#2: 00:00
#3: 00:00
#4: 00:00
#5: 00:00

Device

Dispense Events
Memory Left
Battery Voltage
Battery Count

Treatment: Proventil - 2 Dispensed TID

FIG. 28

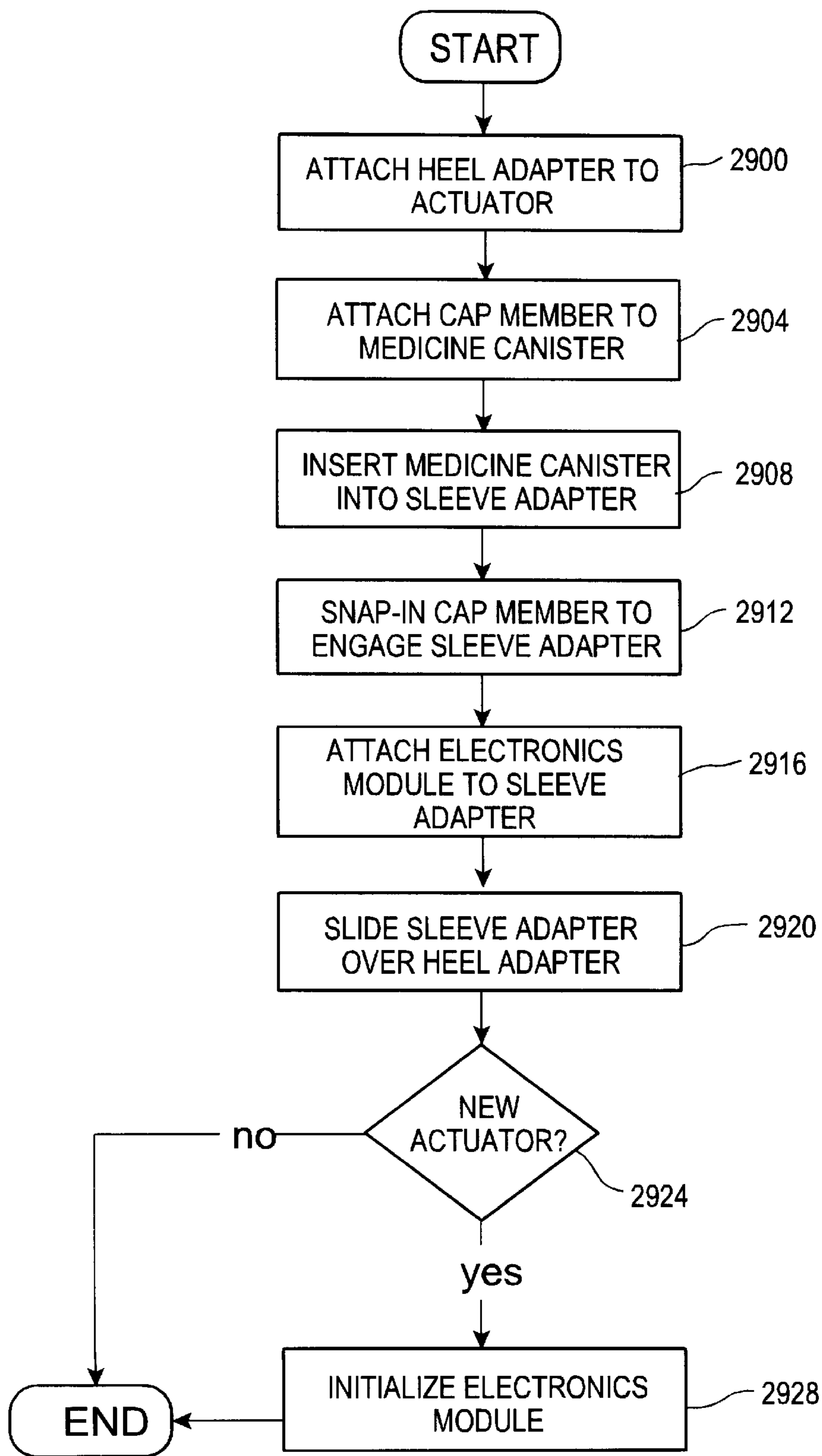


FIG. 29

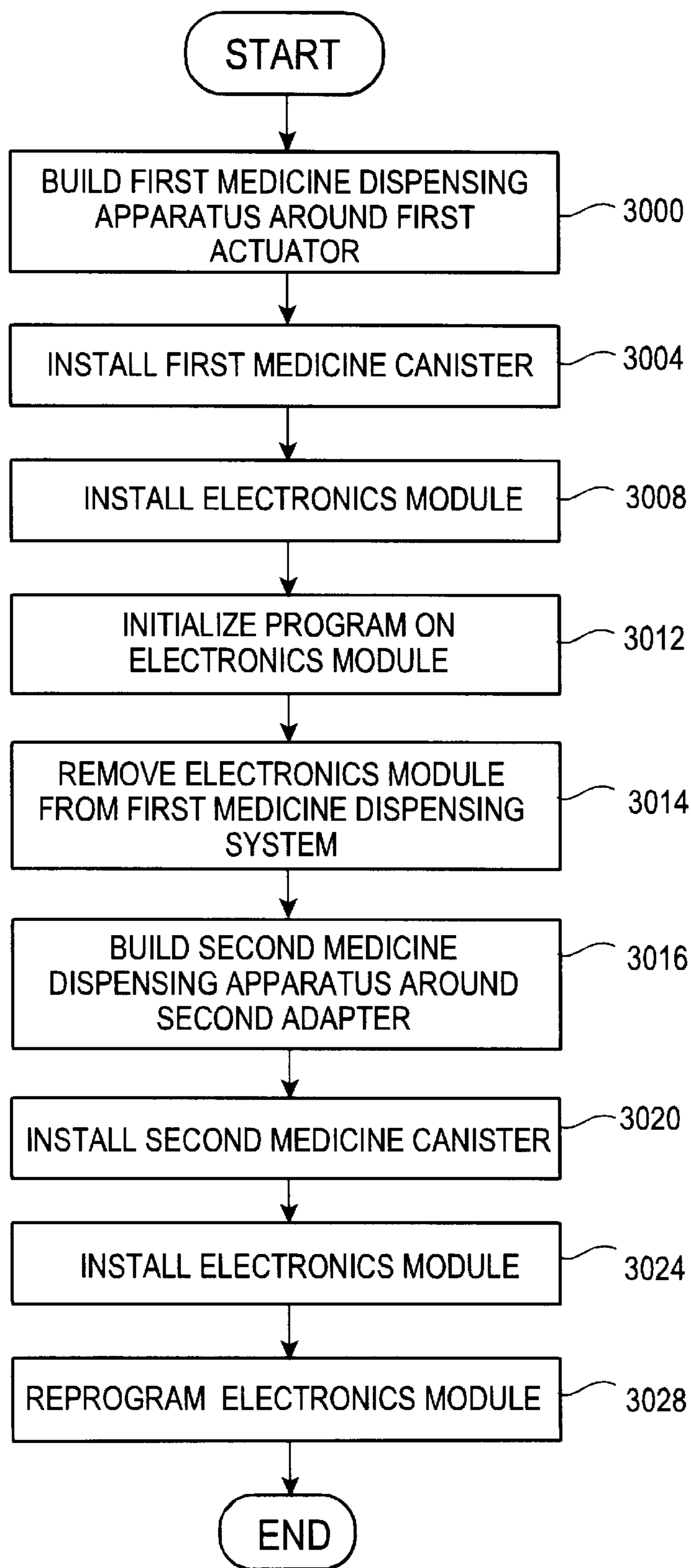


FIG. 30

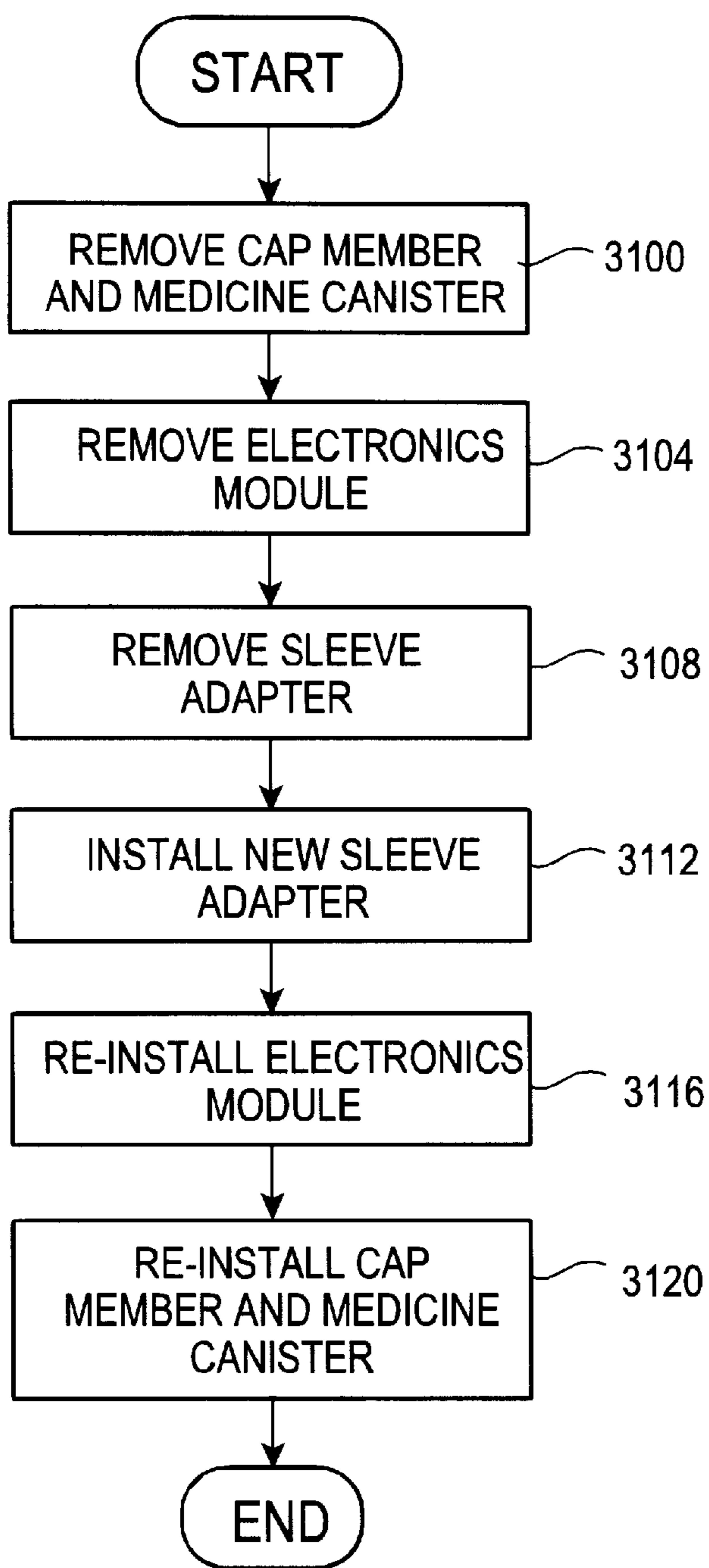


FIG. 31

ELECTRONIC MONITORING MEDICATION APPARATUS AND METHOD

FIELD OF THE INVENTION

The present invention relates to prescribed medication monitoring, and in particular, to an apparatus and method related to a metered dose inhaler which includes an electronics module.

BACKGROUND OF THE INVENTION

Metered dose inhalers of various configurations are known for dispensing medication into the mouth of a patient. The medication is expelled from an actuator and inhaled by the patient, whereupon, the medication is absorbed in the mouth, throat and lungs. A medicine canister is inserted into the actuator so that the actuator may direct the flow of medication out a mouthpiece. The medicine canister is a small pressurized container with a nozzle. By pressing the nozzle, the contents of the canister are dispensed.

Some actuators have integral electronics which monitor various factors related to the dispensing of medication. The timing of the inhalation with respect to the dispensing of medication is important to assure delivery of the medication. The number of times medication is dispensed is also important to monitor. If the actuator is changed, however, the electronics integral to the actuator cannot be reused.

Actuators are standard components provided by many different manufacturers which have a variety of geometric configurations. For example, medicine canisters of different sizes require unique actuators. Further, some medicine manufacturers use proprietary actuators of unique configurations. Additionally, other factors dictate different configurations of actuators such that there is no standard actuator which can dispense all medications.

Applying a non-dedicated electronics module to a variety of actuators of different configurations is described in U.S. Pat. No. 5,809,997, which is assigned to the same assignee as the present application. With the electronics module adaptable to different actuators, this module can be reused, when a different actuator is utilized. In accordance with this previous design, to measure the timing of inhalation and use the non-dedicated electronics module, the actuator needs to be modified. A hole must be formed in the body of the actuator body to allow insertion of an air flow sensor in the path of the patient's inspiration and/or expiration. It would be advantageous to provide a combination of an electronics module and actuator hardware that further facilitates their use and interchangeability.

SUMMARY OF THE INVENTION

In accordance with the present invention, an apparatus and method related to a metered dose inhaler which includes an electronics module is disclosed. In one embodiment, a system for dispensing medication includes: a medicine canister that contains medicine to be dispensed, an actuator that houses the medicine canister and an adapter assembly that allows for obtaining information. The adapter assembly includes a connector assembly and an electronics module. The connector assembly connects to the medicine canister. The electronics module obtains information related to patient usage of medicine in the medicine canister.

In another embodiment, a method for using the same electronics module with two different medicine dispensing apparatuses is disclosed. A first medicine dispensing apparatus includes a first medicine canister which contains a first

medicine. First information, related to dispensing the first medicine, is stored with an electronics module joined to the first medicine dispensing apparatus. A second medicine dispensing apparatus includes a second medicine canister containing a second medicine. The electronics module is removed from the first medicine dispensing apparatus and joined to the second medicine dispensing apparatus. Second information, related to dispensing the second medicine, is stored with the electronics module.

Based upon the foregoing summary, a number of important advantages of the present invention are readily discerned. A single electronics module may be reused even if the actuator changes. Additionally, no modifications are necessary to modify the actuator in order to connect the electronics module thereto.

Additional advantages of the present invention will become readily apparent from the following discussion, particularly when taken together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front perspective view of an embodiment of the medicine dispensing system;

FIG. 2 is a back perspective view of an embodiment of the medicine dispensing system;

FIG. 3 is a block diagram illustrating an embodiment of a patient management system;

FIG. 4 is a block diagram depicting the medicine dispensing system and the docking station;

FIG. 5 is an exploded perspective view of one embodiment of the medicine dispensing system;

FIG. 6 is a partially exploded view of an embodiment of the medicine dispensing system;

FIG. 7 is a perspective view of the sleeve adapter portion of the medicine dispensing apparatus;

FIG. 8 is a back elevational view of the sleeve adapter of FIG. 7;

FIG. 9 is a side elevational view of the sleeve adapter of FIG. 7;

FIG. 10 is a top plan view of the sleeve adapter of FIG. 7;

FIG. 11 is a back perspective view of a heel adapter portion of the medicine dispensing apparatus;

FIG. 12 is a back elevational view of the heel adapter of FIG. 11;

FIG. 13 is a side elevational view of the heel adapter of FIG. 11;

FIG. 14 is a top plan view of the heel adapter of FIG. 11;

FIG. 15 is a back elevational view of an electronics module of the medicine dispensing system;

FIG. 16 is a front elevational view of the electronics module of FIG. 15;

FIG. 17 is a side elevational view of the electronics module of FIG. 15;

FIG. 18 is a front perspective view of the battery and actuation switch element subassembly;

FIG. 19 is a back elevational view of the medicine dispensing apparatus;

FIG. 20 is a side sectional view along the I—I cross section of FIG. 19 which also includes the electronics module;

FIG. 21 is an enlarged portion II of FIG. 20 which shows the spring member deactivated;

FIG. 22 is the enlarged portion II of FIG. 20 which shows the spring member activated;

FIG. 23 is a perspective view of the docking station for the medicine dispensing system;

FIG. 24 is a top plan view of the docking station of FIG. 23;

FIG. 25 is a back elevational view of the docking station of FIG. 23;

FIG. 26 is a side elevational view of the docking station of FIG. 23;

FIG. 27 is an exploded perspective view of the docking station of FIG. 23;

FIG. 28 is a hard copy of display from a practitioner's software program which resides on a medical workstation;

FIG. 29 is a flow diagram showing an embodiment of the steps for assembling and programming the medicine dispensing system;

FIG. 30 is a flow diagram showing an embodiment of the steps for changing actuators; and

FIG. 31 is a flow diagram showing an embodiment of the steps for changing the battery for an embodiment of the medicine dispensing system.

DETAILED DESCRIPTION

With reference to FIGS. 1 and 2, embodiments of the medicine dispensing system 100 are shown in front and back perspective views. The medicine dispensing system 100 includes an actuator 104, a heel adapter 108, a sleeve adapter 112, an electronics module 116, and a cap member 120. Included in a medicine dispensing apparatus 124 is the heel adapter 108, sleeve adapter 112, electronics module 116, and cap member 120. In other words, the medicine dispensing apparatus includes everything in the medicine dispensing system 100 except the canister 500, actuator 104 and electronics module 116. To allow monitoring the use of the medicine, the actuator 104 is modified by adding the heel adapter 108, sleeve adapter 112, electronics module 116, and cap member 120.

With reference to FIG. 3, a patient management system 316 is shown in block diagram form. The management system 316 includes the medicine dispensing system 100, a docking station 300, an user computer 304, and a medical workstation 308. When docked, the medicine dispensing system 100 communicates with the docking station 300

through wired or wireless methods. Preferably, infra-red (IR) transceivers are used to wirelessly communicate between the medicine dispensing system 100 and docking station 300. The docking station 300 is also coupled a user computer 304 which includes a first modem. Information is relayed between the first modem and a second modem in the medical workstation 308. The first and second modems may either directly connect through the plain old telephone system (POTS) network 312 or through a general purpose packet network, such as the Internet. Software on the medical workstation 308 communicates with software on the user machine 304 to allow programming of the medicine dispensing system 100 and retrieving data therefrom. The retrieval of data from the medical dispensing system 100 does not necessarily remove those data from the medical dispensing system 100. However, commands from the medical workstation 308 can erase those data.

Referring next to FIG. 4, a block diagram of the electronics included in the medicine dispensing system 100 and docking station 300 are shown. A first IR transceiver port 400 communicates with a second IR transceiver port 404 by way of a wireless signal 408.

The format of the wireless signal 408 is bi-directional simplex transmission formatted as messages sent a byte at a time. Each message begins with a "wake-up" pulse of 20 μ s, includes multiple message bytes and ends with an "end-of-message" pulse. Each message byte contains a start bit, 8 data bits and a stop bit. Bits are narrow 2 μ s pulses which are separated from each other by 61 μ s. The baud rate of the communication is 9,600.

The protocol of the wireless signal 408 is a master and slave protocol where the master initiates all communications by issuing commands, i.e., where the slave will not speak until spoken to. Since this is a simplex protocol, the master must wait for a complete response from the slave before issuing the next command. The slave generally responds to the commands from the master within one second. If the checksum in the message is bad, the master will issue the command again. In this embodiment, the docking station 300 is the master and the medicine dispensing system 100 is the slave.

The general message protocol is one or more characters followed by a checksum and carriage return <CR>. All characters are encoded in ASCII format. Table I shows the commands for this protocol and Table II shows the data dictionary for the messages.

TABLE I

Command Definitions			
NAME	COMMAND	RESPONSE	PURPOSE
Battery Get	b	<BAT>	To get current battery voltage and usage count since last changed.
Battery Clear	B0	<ACK>	To clear the battery usage count after installing a new battery.
Canister Get	c	<CAN>	To get the current canister usage remaining count.
Canister set	C<CAN>	<ACK>	To preset the correct number of doses available in the canister for the current medication.
Get Record N	d<RECNO>	<RECNO><RECORD>	To get a data log record
Set Record N	D<RECNO><RECORD>	<ACK>	Generate a test data record utilizing input record for data.
Header Set	H<HEADER>	<ACK>	Set header which is a text field to be used by the display

TABLE I-continued

<u>Command Definitions</u>			
NAME	COMMAND	RESPONSE	PURPOSE
Header Get	h	<HEADER>	software as desired. Get header which is a text field to be used by the display software as desired.
Product ID Get	i	<ID><FIRM>	Get product id string with model and serial number and software revision (from ROM).
Product ID Set	I0<ID>	<ACK>	Set product id string with model and serial number. Needs 0 to validate the command. Note firmware <FIRM> is not set with this command.
Canister Reset	K	<ACK>	Initiate canister replacement re-setting counts.
Calibration Set	LO<HRES> <VOLT>	<ACK>	Set inhalation threshold and new battery voltage baseline.
Calibration Get	I	<THRESHOLD> <VOLTAGE>	Get inhalation threshold and new battery voltage baseline settings.
Medication Set	M<MEDNAME>	<ACK>	Set patient medication text for display and number for flow calibration.
Medication Get	m	<MEDNAME>	Get patient medication text for display and number for flow calibration.
Options Set	O<OPTIONS>	<ACK>	Set training and display options according to <options> definition. Generally used for display and alarm control.
Options Get	o	<OPTIONS>	Get training and display options according to <options> definition. Generally used for display and alarm control.
Patient Set	P<NAME>	<ACK>	Set patient name text for display.
Patient Get	p	<NAME>	Get patient name text.
Reminder Set	R<REMINDERS>	<ACK>	Set reminders for usage and docking.
Reminder Get Status	r s	<REMINDERS> <DEVTYPE><STATUS> 	Get current reminders. Provide a handshake and to provide the interpreter or application program with device battery level data information on operational errors encountered since last query.
Time Set	T<YR><DATE/ TIME>	<ACK>	Set GMT time/date and time zone of device relative to GMT.
Time Get	t	<YR><DATE/TIME> 	Get GMT time/date and time zone of device relative to GMT
Get Usage Count	u	<USE>	Get usage count since last clearing of log.
Set Usage Count	UO	<ACK>	Clear usage count and data log. 0 is utilized as verification of command.
Variable Set	V<VN> <HEADER>	<ACK>	Set header number N which is a text field to be used by the display software as desired.
Variable Get	v<VN>	<HEADER>	Get header number N which is a text field to be used by the display software as desired.

TABLE II

<u>Data Dictionary</u>		
FIELD	DETAIL	EXPLANATION
<ACK>	<CR> or <ERR><CR>	no error response error response
<BAT>	VVUUUU	VV: 2 character voltage range 0.0–3.5. UUUU: 4 character usage count.
<CAN>	NNNN	4 digit count of current canister contents.

TABLE II-continued

Data Dictionary		
FIELD	DETAIL	EXPLANATION
<DATA>	<XX>	2 digits hexadecimal event data
	Bit. #	Desc.
	7	Test event
	6	medication dispensed
	5	inhale true
	4	shake true
	3	multiple dose
	2	late inhale
	1,0	# tics to inhale
	<DATE/TIME>	MMDDHHMMSS
<DEVTYPE>	C	Indicates Device Type
<DISPSTAT>	<XX>	2 digits hexadecimal internal Electronics
	Bit. #	Module status
	7	Desc.
	6	disable logging
	5	inhale delay warm-up
	4	inhale delay
	3	dispense check in-process
	2	arm check
	1	inhale check in process
	0	armed
	<optional checksum><CR>	end of message
<ERR>	0	no error same as only <CR>
	1	not understood
	2	checksum error
	3	format error
<FIRM>	C4	4 character Firmware revision from Processor ROM i.e. 0F00
		Byte 1 is a variation code
		Byte 2 is Firmware revision
		Bytes 3-4 intermediate engineering release #
<HEADER>	<C28>	28 character display program specific info.
<ID>	<C12>	12 character product id and serial number
		"rr" is the circuit board assembly revision number, "bbbb" is the four digit circuit board batch number, "\$" is the circuit board assembly serial number.
		2 digits hexadecimal internal electronics
		module status
<MDISTAT>	<XX>	Desc.
	Big. #	Time to Log
	7	shake
	6	inhale correct
	5	inhaled late
	4	medication delivery
	3	multiple
	2	advance
	1	reminder time
	0	2 digits hexadecimal internal electronics
<MDISTAT_E>	<XX>	module status
	Bit. #	Desc.
	7	no start bit
	6	log full
	5	QC time
	4	battery low
	3	canister empty
	2	beep high
	1	menus enabled
	0	diagnostic mode
<MEDNAME>	<C16>	16 character name
<NAME>	<C16>	16 character name
<OPTIONS>	<XX>	2 digits hexadecimal mask
	Bit. #	Feature.
	0	Display level 0 Basic
	1	Display level 1 Enhanced Time/Canister
	2	Display level 2 patient info submenu
	3	Display level 3 device info submenu
	4	Patient info feedback
	5	Audible reminders
	6,7	00 - Standard MDT
		10 - Autohaler logic
	11 - Non MDI device no inhale test	
	NOTE: Level 1 must include level 0	
	Level 2 must include level 0	

TABLE II-continued

Data Dictionary		
FIELD	DETAIL	EXPLANATION
<RANGE>	<BBBBEEEE>	BBBB: 4 digit hex begin address EEEE: 4 digit hex ending address
<RECNO>	NNNN	4 digit decimal record number
<RECORD>	<DATE/TIME><DATA>	Month/day etc. Data record
<REMINDERS>	<HHMMHHMMHHMM HHMMHHMMHHMM>	HH: 2 digit hour MM: 2 digit minute of hour item 1-5 dose reminders item 6 docking reminder Unset alarms must be set to 9999 as 0000 is midnight in 24 hour format.
<STATUS>	<MDISTAT><MDISTAT_E><DTSP_STAT> <NOTDEFINED><NOTDEFINED><NOTDEFINED>	
<USE>	NNNNLLLL	NNNN: 4 digit count number of uses LLLL: 4 digit count of uses available (left in memory)
<VN>	N	Single digit variable number
<YR>	YY	2 digit year

In this embodiment, the electronics in the medicine dispensing apparatus **100** are divided between the sleeve adapter **112** and the electronics module **116**. The sleeve adapter **112** houses a battery **412** (for example, a 3 V_{DC} coin-shaped battery) and an actuation switch element **416**. The electronics module **116** includes the first IR port **400**, an air flow sensor **420**, a shake sensor **424**, a first controller **428**, memory **432**, menu buttons **436**, a first display **440**, and a speaker **444**.

The first controller **428** manages the operation of the electronics through embedded software or firmware. The time and date of activation of the actuator **104** is recorded in the memory **432**. The memory **432** may be volatile or non-volatile and may serve as the exclusive storage device or be supplemented by other memory in the first controller **428**. In this embodiment, the memory **432** is 4 Kbytes and stores 1,320 actuation events.

The actuation switch element **416** detects dispensing of medication. During use, the mouth of the actuator is placed in the mouth of the patient, whereafter, the sleeve adapter **112** is pressed toward the mouthpiece to activate a dispensing valve in the medicine canister. When the sleeve adapter **112** is pressed, the actuation switch element **416** integral to the sleeve adapter **112** detects the dispensing of medication. The time of dispensing is recorded by the first controller **428**. The actuation switch element **416** has a spring member which completes a circuit when the sleeve adapter **112** slides toward the heel adapter **108** so that dispensing may be recorded. In this embodiment, up to two dispensing per second can be recorded in this way.

The air flow sensor **420** measures the inspiration which pulls the medication aerosol into the mouth of the patient. In this embodiment, a heated thermistor is used to measure air flow. The heated thermistor in the air flow sensor **420** is cooled by the air flow. The time and amount of cooling may be measured and recorded by the first controller **428**. To conserve memory space, a flag may be used to indicate the presence of sufficient inspiration proximate in time to the dispensing of medication instead of recording time and amount. Fifteen liters per minute of inhalation or more can be detected with this sensor.

Shaking of the medicine dispensing apparatus **100** is recorded by the shake sensor **424**. Prior to dispensing, shaking of the medicine canister mixes the contents to assure

efficacy of some medications. In one embodiment, the shake sensor **424** includes a sliding magnet which moves when the medicine dispensing apparatus **100** is shaken to produce a signal indicative of the movement. Other types of sensors, such as accelerometers, could also be used to record the shaking. To record this event, a flag is stored which indicates a successful shaking before dispensing medication. Shaking which is not followed by actuation of the dispenser **100**, is not recorded to conserve memory.

The first display **440** provides status information and prompts to the patient. In one embodiment, the display is a liquid crystal display (LCD) with two lines where each has eight characters. The first display **440** provides information such as the patient's name, medication name, dose count, current time and date, number of remaining doses, time of last use, time of next use, low medication reminder, low battery reminder, battery level, device identifier or serial number, and memory capacity remaining. Menu buttons **436** allow scrolling through menu options and selecting features. In this embodiment, the menu buttons **436** are membrane switches.

A speaker **444** is provided to allow auditory feedback from the electronics module **116**. The speaker **444** could produce an alarm when a dose of medication were required. Other interactions between the patient and electronics module **116** could be enhanced with auditory feedback from the speaker **444**.

The docking station **300** serves as a conduit of the medical workstation **308**. Once the medication delivery system **100** is placed in the docking station **300**, the data stored in memory is retrieved and any programming or reprogramming of the medication delivery system **100** takes place. Programming is needed for a newly issued electronics module **116** and reprogramming is required when the electronics module **116** is attached to a different actuator **104**. The docking station **300** includes the second IR port **404**, a second controller **448**, a communication port **452**, a second display **456**, menu buttons **460**, and a power supply **464**. The second IR port **404** communicates with the first IR port **400** when the medicine dispensing system **100** is docked by way of the wireless signal **408**.

The operation of the docking station is managed by the second controller **448**. Firmware in the controller **448** receives and processes information from the communication

port 452, second IR port 404 and menu buttons 460. Additionally, output for the display 456, second IR port 404 and communication port 452 is prepared by the controller 448.

The communication port 452 provides a conduit to the user computer 304 and, ultimately, the medical workstation 308. In one embodiment, the communication port 452 is a standard serial port (i.e., RS-232) commonly found on computers. Software on the user machine 304 allows interaction with the communication port 452 so that programming information and data may pass therethrough.

The docking station 300 also contains a second display 456 and menu buttons 460. The second display 456 could be a LCD, or other type of display. Status information and user prompts could be displayed to assist the patient. For example, error messages could be displayed instructing the patient to reseal the medicine dispensing system 100 in order to allow for better IR communication. The menu buttons 460 allow interaction between the docking station 300 and patient. In one embodiment, the menu buttons 460 are membrane switches.

Power is supplied to the docking station 300 from a power supply 464. Either an external transformer or internal batteries provide energy to the power supply 464. Further conditioning of these two power sources is provided by the power supply 464 to produce, for example, 5 V_{DC} for the circuitry within the docking station 300.

With reference to FIG. 5, an exploded view of the medicine dispensing system 100 is shown. Included in the medicine dispensing apparatus 100 is a connector assembly, the electronics module 116, the medicine canister 500, and the actuator 104. The connector assembly includes the cap member 120, a double-sided tape 504, the sleeve adapter 112, and the heel adapter 108. The cap member 120, double-sided tape 504, and sleeve adapter 112 move with the medicine canister 500 to dispense the medicine through a mouthpiece 524. In this embodiment, the cap member 120, sleeve adapter 112 and heel adapter 108 are made of molded plastic.

The cap member 120 is attached to the canister 500 with a double-sided tape 504. The cap member 120 has the double-sided tape 504 pre-attached. A liner covers the side of the tape 504 which will eventually attach to the canister 500. A release tab 508 is included in the double-sided tape 504 which eases removal of the liner to expose the adhesive tape 504 beneath. Upon removal of the liner, the canister 500 is pressed against the double-sided tape 504 to affix the cap member 120 to the canister 500. Once the double-sided tape 504 is affixed between the cap member 120 and medicine canister 500, the whole assembly may be slid into an opening 520 in the sleeve adapter 112. Snaps 528 around the periphery of the cap member 120 snap into the sleeve adapter 112 to affix the two together. In other embodiments however, the cap member 120 could screw into the sleeve adapter 112 to interconnect the two.

The sleeve adapter 112 has a window 512 for viewing a medication label and connectors 516 for attaching the electronics module 116. The window 512, integral to the sleeve adapter 112, allows reading any prescription information on the medicine canister 500 by rotating the cap member 120. The electronics module 116, in this embodiment, also includes the actuation switch element 416 and battery 412. The connectors 516 removably attach the electronics module to the sleeve adapter 112. A tool such as a flat-head screw driver can be used to pry the connectors 516 away from the electronics module 116. When the battery 412 is depleted in

one embodiment, the battery 412 and all other components, except for the electronics module 116, are replaced since such components are disposable and for sanitary reasons this is preferred. In another embodiment, the battery only could be replaced when its charge is depleted and is not rechargeable.

The heel adapter 108 is attached to the body of the actuator 104. Snaps on the heel adapter 108 attach around the back and bottom of the actuator 104. After installation of the heel adapter 108, a mouthpiece of the actuator is not obstructed in any way. In this embodiment, no modification of the actuator is necessary for attaching the heel adapter 108 and sleeve adapter 112. The heel adapter 108 guides the sleeve adapter 112 and provides a back-stop for the spring member which senses actuation of the medicine dispensing system 100.

With reference to FIG. 6, an embodiment of the medicine dispensing system 100 is shown in an exploded view. The medicine canister 500 is engaged with the cap member 120. In this embodiment, the battery 412 and actuation switch element 416 are integral to the sleeve adapter 112. Electrical contacts 600 allow coupling the battery 412 and spring member to the electronics module 116. The menu buttons 436 and the first display 440 are shown on the electronics module 116.

Referring to FIGS. 7–10, the sleeve adapter 112 is respectively shown in perspective, back, side and top views. The cap member 120 is shown attached to the sleeve adapter 112. In this embodiment, the battery 412 and actuation switch element 416 are integral to the sleeve adapter 112. When the battery 412 expires, the whole sleeve adapter 112 is removed and replaced, and it is recommended, everything but the electronics module 116 also be replaced. The sleeve adapter surrounds at least a majority of a perimeter of the actuator.

With reference to FIGS. 11–14, the heel adapter 108 is respectively shown in perspective, back, side and top views. Included in the heel adapter 108 are vertical connectors 1300, horizontal connectors 1400 and a switch engaging member 1404. The vertical connectors 1300 wrap around the bottom of the actuator 104 and the horizontal connectors 1400 wrap around the front of the actuator 104. When the sleeve adapter 112 is compressed to dispense medication, the switch engaging member 1404 presses against the spring member to close the actuation switch 416. In this way, the dispensing of medication is recorded. The sleeve adapter 124 snaps together with the heel adapter 108.

Referring next to FIGS. 15–17, an embodiment of the electronics module 116 is respectfully shown in backs front and side views. A scroll button 1500 and a select button 1504 comprise the two menu buttons 436. The scroll button 1500 allows cycling through the various menus and options and the select button 1504 allows selection of those options. To allow the IR communication of the first IR port 400, an IR transmitter and receiver 1512, 1516 are provided. When docked, the IR elements 1512, 1516 face a conjugate pair of IR elements to allow communication. Latches 1508 are provided which mate with connectors 516 on the sleeve adapter 122. The latches allow removably attaching the electronics module 116 to the sleeve adapter 122. Although not shown in FIG. 16, the front of the electronics module 116 includes connectors which mate to the electrical contacts 600 on the battery and actuation switch element subassembly. Removal of the electronics module 116 renders portions of the medicine dispensing system 100 functionally inoperable.

With reference to FIG. 18, a perspective view of a battery and actuation switch element assembly 1800 is shown. In

this embodiment, the battery and actuation switch element assembly **1800** is installed integrally to the sleeve adapter **112**. The battery and actuation switch element assembly **1800** includes a spring member **1804**, a circuit board **1808**, and the battery **412**. Electrical contacts **600**, on the side of the circuit board **1808** away from the spring member **1804**, couple the battery and actuation switch element assembly **1800** to the electronics module **116**. When the sleeve adapter **112** is pressed toward the heel adapter **108**, the spring member **1804** is temporarily bent by the switch engaging member **1404** to complete an electrical loop. In this way, dispensing of the medication is detected.

Referring to FIG. **19**, a back view of the medicine dispensing apparatus is shown. The battery and actuation switch element assembly **1800** is shown installed in the sleeve adapter **112**. In one embodiment, two fasteners **1900** are threaded through the circuit board **1808** to affix the battery and actuation switch element assembly **1800**. Alternatively, the circuit board **1808** could be ultrasonically staked to the sleeve adapter **112**. It is noted, other embodiments integrate the battery and actuation switch element assembly **1800** into the electronics module **116**.

FIGS. **20–22** detail the operation of the actuation switch element **416**. FIG. **20** shows a side sectional view along the I—I cross section of FIG. **19** which also includes the electronics module. Section II of FIG. **20** is enlarged in FIGS. **21** and **22** to show the action of the spring member **1804** in greater detail. FIG. **21** illustrates the spring member **1804** in an uncompressed position. Alternatively, FIG. **22** illustrates the spring member **1804** in a compressed position which corresponds to the dispensing of medicine.

With reference to FIGS. **23–26**, an enclosure **2300** of the docking station **300** is respectively shown in perspective, top, back, and side views. The enclosure **2300** includes a docking cradle **2304**, an IR window **2308**, a communication cable **2312**, the second display **456**, the menu buttons **460**, a communication port **2500**, a direct current power input **2504**, and a reset button **2508**. The docking cradle **2304** is shaped to receive the electronics module **116** in a such a way that the IR window **2308** is proximate to the IR transmitter and receiver **1512**, **1516** on the electronics module **116**. Behind the IR window **2308** is another IR transmitter and receiver which are used to couple the docking station **300** to the electronics module **116**. The display **456** presents information to the patient and the menu buttons **460** allow interaction with any displayed information. To allow serial communication with the user computer **304**, the communication cable **2312** is plugged into the communication port **2500**. The direct current power input **2504** receives power from an external transformer which is coupled to an alternating current wall outlet. In order to recover from firmware crashes in the controller **448**, the reset button is able to reset the circuitry within the docking station **300**.

Referring next to FIG. **27**, an exploded view of the docking station **300** is shown. The enclosure **2300** is comprised of a bottom **2708**, top **2724**, front panel **2720**, back panel **2716** and guide plate **2728**. Included within the enclosure are an electronics printed circuit board (PCB) **2700**, batteries **2704** and a battery holder **2712**. The electronics PCB **2700** includes the battery holder **2712**, communication port **2500**, direct current power input **2504**, and reset button **2508** and further includes the circuitry for the communications port **452**, second IR port **404**, controller **448**, and power supply **464**. To provide redundant power, batteries **2704** may be inserted into a battery holder **2712**. Battery power is used when there is no power applied to the direct current power input **2504**.

With reference to FIG. **28**, a hard-copy of a display from the practitioner's software is shown. The practitioner's software is updated with data from the medicine dispensing system **100**. The data is updated by the patient management system **316** when the medicine dispensing system is docked. The data may be charted and otherwise analyzed with the practitioner's software. The medical practitioner can manage a number of patients with this software.

Additionally, the practitioner's software allows programming and reprogramming of the medicine dispensing system **100**. The medicine type, number of doses, puffs per dose and timing of doses can be programmed into the medicine dispensing system **100** by the practitioner's software. Reminders can also be programmed into the medicine dispensing system **100** which notify the patient when medication is needed by way of the speaker **444** or first display **440**. Upon receiving a new medicine dispensing system **100**, the patient docks the system **100** to have the programming performed. If the electronics module **116** is ever transferred to another medicine dispensing apparatus, the electronics module **116** is reprogrammed in a similar way.

Referring to FIG. **29**, a flow diagram of the steps for assembling the medicine dispensing system **100** for one embodiment are shown. In step **2900**, the heel adapter **108** is attached to the actuator **104**. The vertical connectors **1300** snap around the bottom of the actuator **104** and the horizontal connectors **1400** snap around the front of the actuator **104**. In step **2904**, the cap member **120** is attached to the medicine canister **500**. The double-sided tape **504** is used to affix the cap member **120** and medicine canister **500** together. In steps **2908** and **2912** the cap member **120** is affixed to the sleeve adapter **112**. The medication canister **500** is inserted into the sleeve adapter **112** and the cap member is **120** snapped together with the sleeve adapter **112**. In alternative embodiments, the cap member **120** could screw into with the sleeve adapter **112**. In step **2916**, the electronics module **116** is attached to the sleeve adapter **112**. Connectors **516** retain the electronics module **116** to the sleeve adapter **112**. After the assembly of the electronics module **116**, cap member **120**, medicine canister **500** and sleeve adapter **112** is complete, the sleeve adapter **124** is slid over the heel adapter **108** in step **2920** until the two snap together. The shape of the heel adapter **108** forces the window **512** of the sleeve adapter **124** to face forward. To view a medication label on the canister **500**, the sleeve adapter **124** with attached cap member **120** and canister **500** are removed from the remainder of the medicine dispensing system **100**. Then, the cap member **120** is turned to rotate the label on canister **500** into view through the window **512**.

If the actuator **104** is new to the user, the electronics module **116** receives new programming. The actuator **104** could be entirely new to the patient and require programming, or the actuator **104** could merely be a change in medication and require reprogramming only. If the actuator **104** is the same or a replacement having the same configuration as the old actuator **104**, no programming is required and the medicine dispensing system **100** is complete. A determination is made in step **2924** as to whether the actuator **104** is new to this patient and would need programming or reprogramming. In step **2928**, programming or reprogramming of the electronics module **116** is performed by mating the medicine dispensing system **100** to the docking station **300**, as described above.

With reference to FIG. **30**, a flow diagram of the steps for changing to a different actuator **104** is shown. Changing to a different actuator **104** requires reprogramming the electronics module **116** accordingly for any new dosage regi-

ment. In step 3000, the medicine dispensing apparatus is built. The first medicine canister is installed in step 3004. Next, the electronics module 116 is attached to the sleeve adapter 112 in step 3008. Once the building of the medicine dispensing system 100 is complete, the system is programmed the first time in step 3012. In between steps 3012 and 3014, a different medication and/or actuator 104 are provided to the patient. In step 3014, the electronics module 116 is salvaged from the first medicine dispensing system 100. Removal of the electronics module 116 typically damages the connectors 516 which retain the module 116. Accordingly, the damaged connectors render the sleeve adapter 112 unusable which is desirable for sanitation reasons. In steps 3016, 3020, and 3024, the second medicine dispensing apparatus is built. In this embodiment, the first medicine dispensing apparatus has a different mechanical configuration than the second medicine dispensing apparatus. Different heel and sleeve adapters 108, 112 are shaped to accommodate the different mechanical configuration. The heel and sleeve adapters 108, 112 from the first actuator have a geometric configuration which generally prevents them from being properly installed on the second actuator. The electronics module 116 is reprogrammed in step 3028 to accommodate the new dosage guidelines. In this way, a single electronics module 116 may be interchanged between a variety of actuators 104.

Referring to FIG. 31, the steps for replacing the battery 412 for one embodiment is shown. In this embodiment, the battery 412 is integral to the sleeve adapter 112 so that the whole sleeve adapter 112 is disposed of to replace the battery 412. In steps 3100, 3104, and 3108, the cap member 120 and medicine canister 500, the electronics module 116 and sleeve adapter 112 are successively removed. A new sleeve adapter 112 with a new battery 412 is installed in step 3112. The electronics module 116 and cap member 120 and medicine canister 500 are reinstalled in steps 3116 and 3120 to complete the battery 412 replacement process. However, in embodiments where the cap member 120 snaps into the sleeve adapter 112, an assembly of the cap member 120, sleeve adapter 112 and medicine canister 500 are removed together in a single step.

The foregoing discussion of the invention has been presented for purposes of illustration and description. Further, the description is not intended to limit the invention to the form disclosed herein. Consequently, variations and modifications commensurate with the above teachings, within the skill and knowledge of the relevant art, are within the scope of the present invention. By way of example only, the invention need not be limited to dispensing liquid aerosol medications. Other applications can be implemented incorporating the principles of the present invention including dispensing dry powder medications. The embodiments discussed hereinabove are further intended to explain the best mode known of practicing the inventions and to enable others skilled in the art to utilize the inventions in such, or in other embodiments and with the various modifications required by their particular application or uses of the Inventions. It is intended that the appended claims be construed to include alternative embodiments to the extent permitted by the prior art.

What is claimed is:

1. In a system for dispensing medication that includes a medicine canister that contains medicine to be dispensed, an actuator that houses the medicine canister, and an adapter assembly for obtaining information, said adapter assembly comprising:

a connector assembly connected to said actuator when information related to patient usage of the medicine in

the medicine canister is being obtained, at least portions of said connector assembly move with the medicine canister when the medicine canister is moved to dispense medicine to the patient; and

an electronics module on said connector assembly for obtaining the information related to patient usage of the medicine.

2. In a system for dispensing medication that includes a medicine canister that contains medicine to be dispensed, an actuator that houses the medicine canister, and an adapter assembly for obtaining information, said adapter assembly comprising:

a connector assembly connected to said actuator when information related to patient usage of the medicine in the medicine canister is being obtained, said connector assembly including a sleeve adapter surrounding at least a majority of a perimeter of said actuator; and

an electronics module on said connector assembly for obtaining the information related to patient usage of the medicine.

3. In a system for dispensing medication that includes a medicine canister that contains medicine to be dispensed, an actuator that houses the medicine canister, and an adapter assembly for obtaining information, said adapter assembly comprising:

a connector assembly connected to said actuator when information related to patient usage of the medicine in the medicine canister is being obtained, said connector assembly including a heel adapter joined to said actuator and a sleeve adapter joined to said heel adapter and disposed outwardly thereof; and

an electronics module on said connector assembly for obtaining the information related to patient usage of the medicine.

4. In a system for dispensing medication that includes a medicine canister that contains medicine to be dispensed, an actuator that houses the medicine canister, and an adapter assembly for obtaining information, said adapter assembly comprising:

a connector assembly connected to said actuator when information related to patient usage of the medicine in the medicine canister is being obtained, said connector assembly including a cap member connected to a top of the medicine canister; and

an electronics module on said connector assembly for obtaining the information related to patient usage of the medicine.

5. An adaptor assembly, as claimed in claim 4, wherein: said connector assembly includes a sleeve adaptor and said cap member is connected to said sleeve adaptor.

6. In a system for dispensing medication that includes a medicine canister that contains medicine to be dispensed, an actuator that houses the medicine canister, and an adapter assembly for obtaining information, said adapter assembly comprising:

a connector assembly connected to said actuator when information related to patient usage of the medicine in the medicine canister is being obtained; and

an electronics module on said connector assembly for obtaining the information related to patient usage of the medicine, said electronics module including a switch element and said connector assembly including a heel adapter and in which said switch element is moveable relative to said heel adapter.

7. In a system for dispensing medication that includes a medicine canister that contains medicine to be dispensed, an

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actuator that houses the medicine canister, and an adapter assembly for obtaining information, said adapter assembly comprising:

a connector assembly connected to said actuator when information related to patient usage of the medicine in the medicine canister is being obtained; and

an electronics module for obtaining the information related to patient usage of the medicine, said electronics module being removable from said connector assembly and with at least portions of said connector assembly being disposable while said electronics module is reusable.

8. In a system for dispensing medication that includes a medicine canister that contains medicine to be dispensed, an actuator that houses the medicine canister, and an adapter assembly for obtaining information, said adapter assembly comprising:

a connector assembly connected to said actuator when information related to patient usage of the medicine in the medicine canister is being obtained, said connector assembly including a first sleeve adapter and a first heel adapter and in which said first sleeve adapter and said first heel adapter are connected to said actuator but each have a geometric configuration that prevents them from being properly connected to a second actuator; and

an electronics module on said connector assembly for obtaining the information related to patient usage of the medicine.

9. A method for using the same electronics module with two different medicine dispensing apparatuses, comprising:

providing a first medicine dispensing apparatus including a first medicine canister containing a first medicine;

storing first information related to dispensing the first medicine with an electronics module joined to said first medicine dispensing apparatus;

providing a second medicine dispensing apparatus including a second medicine canister containing a second medicine; and

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storing second information related to dispensing the second medicine with said electronics module, with said electronics module being removed from said first medicine dispensing apparatus and joined to said second medicine dispensing apparatus.

10. A method, as claimed in claim **9**, wherein:

said step of providing said second medicine dispensing apparatus includes rendering functionally inoperable connector portions of said first medicine dispensing apparatus with removal of said electronics module from remaining portions thereof.

11. A method, as claimed in claim **9**, wherein:

said first medicine dispensing apparatus includes a first actuator and a first connector assembly for connection to said electronics module and in which said step of providing said second medicine dispensing apparatus includes replacing said first connector assembly with a second connector assembly that is compatible with a second actuator but is not compatible with said first actuator.

12. A method, as claimed in claim **9**, wherein:

said step of storing said second information includes presenting an interface on a computer display screen for inserting information, said interface including identification information and a number of insertion sections for inserting information related to identification of the first medicine and dosages of the first medicine.

13. A method, as claimed in claim **12**, wherein:

said number of insertion sections relate to a number of options in a group that includes: basic functions, time functions, device messages, patient information, and audio.

14. A method, as claimed in claim **12**, wherein:

said step of storing said second information includes communicating said second information to said electronics module using a docking station.

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